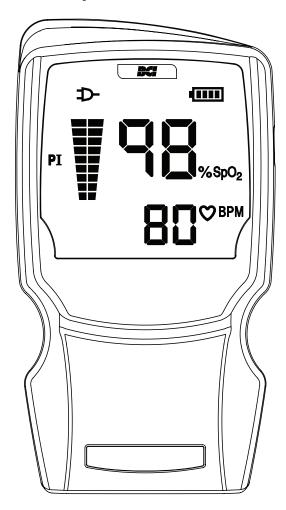


# SPECTRO | 20 SPECTRO | 10

# WW1020/WW1000

**Operation Manual** 



En English Catalog Number WW1922en Version 0, April 2009

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# **Table of Contents**

Warranty and Service Information	v
Proprietary Notice	V
Warranty	V
Limited Warranty	V
Disclaimer of Warranties	V
Conditions of Warranty	V
Limitation of Remedies	V
Warranty Procedure	vi
CE Notice	vi
Chapter 1: Introduction	1-1
About the Manual	
Definition of Symbols	1-1
Warnings	
Cautions	1-7
Notes	1-8
Chapter 2: Intended Use and Monitor Features	
Intended Use for the WW1020 Oximeter	
Intended Use for the WW1000 Oximeter	
Monitor Features	2-1
Theory of Operation	2-2
Pulse Amplitude Index	2-3
Patented Technology (WW1020 only)	2-3
Chapter 3: Controls and Features	3-1
Front Display	
Monitor Operating Key	3-2
Monitor Back and Bottom Panels	
Chapter 4: Operating Instructions	4-1
Unpacking the Monitor	
Powering the Oximeter	
Installing the Batteries	4-3
External Power	4-4
AC Power	4-5
USB Power (Universal Serial Bus)	4-6
Turning On the Monitor	4-7
Checking the Monitor's Configuration	4-8
Checking the Monitor's Performance	4-8
Attaching the Sensor to the Patient	4-9
Choosing the Sensor	4-10
BCI® Sensors	4-10

Nellcor® Sensor (WW1020 Only)	4-11
Cleaning or Disinfecting the Sensors	4-11
Checking the Sensor and Oximetry Cable	4-11
Pulse Amplitude Index	4-12
Storing the Sensor	4-14
Home Use	4-15
Equipment and Supplies Checklist for Home Use	4-15
Training the Home Use Caregiver	4-16
Chapter 5: Patient Record Number and Trend Data	5-1
Description	5-1
Incrementing the Patient Record Number	5-1
Memory Capacity	5-1
Clearing Trend Data	5-1
Trend Data Output	
Chapter 6: Optional Docking Station and Printer	6-1
Description	6-1
Docking Station	6-2
Powering the Docking Station	6-2
WW1090 Lithium-lon (Li+) Rechargeable Battery Pack	6-3
Installing the Oximeter to the Dock	6-3
Downloading Data to PC	
Printer	6-4
Attaching the Printer	6-5
Loading Paper	6-6
Choosing the Print Mode	6-7
Trend Data Condition Flags	6-8
Chapter 7: PC Communication Setup	7-1
Description	
Power Input and Data Connector Port	
How to Set Up Equipment	
Sensor / RS232 Port	
How to Set Up Equipment	7-4
Output Format	7-5
Chapter 8: Maintenance	8-1
Routine Maintenance	
Cleaning and Disinfecting	
Storage	
Chapter 9: Troubleshooting	
Power	
Sensor	
Other	

Chapter 10: Optional Supplies and Accessories	10-1
Ordering Information	10-2
Chapter 11: Specifications	11-1
Displays	
Indicators	
Keys/User Controls	11-1
$SpO_2$ for the WW1020 Oximeter	11-2
Pulse Rate for the WW1020 Oximeter	11-3
SpO <sub>2</sub> for the WW1000 Oximeter	11-4
Pulse Rate for the WW1000 Oximeter	11-5
Pulse Amplitude Index for the WW1020 Oximeter	11-6
Pulse Amplitude Index for the WW1000 Oximeter	11-6
Printer	11-6
Serial Data Output	11-7
Power Input and Data Connector	11-7
Sensor Connector	
Power Requirements	11-7
Battery	
AC Charger	11-7
USB	11-7
Monitor Dimensions	11-7
Dock Dimensions	11-8
Auxiliary Inputs/Outputs	
Environmental	11-8
Equipment Classification	
Design Standards	11-9
Appendix A: Guidance and Manufacturer's Declaration	A-1
Guidance and Manufacturer's Declaration	A-1
Electromagnetic Emissions - Emissions Test	A-1
Electromagnetic Immunity - Immunity Test	
Recommended Separation Distances	A-4

The serial autocorrelation technology (SAC) in the WW1020 oximeter is covered by U.S. Patent No. 5,558,096.

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# **Warranty and Service Information**

# **Proprietary Notice**

Information contained in this document is copyrighted by Smiths Medical PM, Inc. and may not be duplicated in full or part by any person without prior written approval of Smiths Medical PM, Inc. Its purpose is to provide the user with adequately detailed documentation to efficiently install, operate, maintain, and order spare parts for the device supplied. All information contained in this document is believed to be current and accurate as of the date of publication or revision, but does not constitute a warranty.

# Warranty

#### **Limited Warranty**

Smiths Medical PM, Inc. ("Seller") warrants to the original purchaser that the Product, not including accessories, shall be free from defects in material and workmanship under normal use, if used in accordance with its labeling, for three years from the date of shipment to the original purchaser.

Seller warrants to the original purchaser that the reusable oximeter sensors supplied as accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with its labeling, for one year from the date of shipment to the original purchaser (USA only).

#### **Disclaimer of Warranties**

THE FOREGOING EXPRESS WARRANTY, AS CONDITIONED AND LIMITED, IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Seller disclaims responsibility of the suitability of the Product for any particular medical treatment or for any medical complications resulting from the use of the Product. This disclaimer is dictated by the many elements which are beyond Seller's control, such as diagnosis of patient, conditions under which the Product may be used, handling of the Product after it leaves Seller's possession, execution of recommended instructions for use and others.

#### **Conditions of Warranty**

This warranty is void if the Product has been altered, misused, damaged by neglect or accident, not properly maintained or recharged, or repaired by persons not authorized by Seller. Misuse includes, but is not limited to, use not in compliance with the labeling or use with accessories not manufactured by Seller. This warranty does not cover normal wear and tear and maintenance items.

#### **Limitation of Remedies**

The original purchaser's exclusive remedy shall be, at Seller's sole option, the repair or replacement of the Product. THIS IS THE EXCLUSIVE REMEDY. In no event will Seller's liability arising out of any cause whatsoever (whether such cause is based on contract, negligence, strict liability, tort or otherwise) exceed the price of the Product and in no event shall Seller be responsible for consequential, incidental, or special damages of any kind or nature whatsoever, including but not limited to, lost business, revenues, and profits.

# **Warranty Procedure**

To obtain warranty service in the USA, you must request a Return Authorization (RA) number from Technical Service. Reference the RA number when returning your Product, freight and insurance prepaid, to:

 Smiths Medical PM, Inc.
 Phone: (262) 542-3100

 N7W22025 Johnson Drive
 Fax: (262) 542-0718

 Waukesha, WI 53186-1856
 Toll Free: (800) 558-2345

Seller will not be responsible for unauthorized returns or for loss or damage to the Product during the return shipment. The repaired or replaced Product will be shipped, freight prepaid, to Purchaser.

To obtain warranty information outside of the USA, contact your local distributor.

Keep all original packing material, including any inserts. If you need to ship the device, use only the original packaging material, including inserts. Box and inserts should be in original condition. If original shipping material in good condition is not available, it should be purchased from Smiths Medical PM, Inc.

Damages occurring in transit in other than original shipping containers are the responsibility of the shipper. All costs incurred returning devices for repair are the responsibility of the shipper.

#### **CE Notice**

Marking by the symbol **0473** indicates compliance of this device to the Medical Device Directive 93/42/EEC.

EC | REP | Authorized Representative (as defined by the Medical Device Directive):

Smiths Medical International Ltd. Phone: (44) 1923 246434 Colonial Way, Watford, Hertfordshire, Fax: (44) 1923 240273

WD24 4LG, UK

Australian Representative:

Smiths Medical Australasia Pty. Ltd. Tel: +61 (0) 7 3340 1300 61 Brandl Street, Eight Mile Plains, QLD 4113, Australia

# **Chapter 1: Introduction**

#### **About the Manual**

The Clinician's Operation Manual provides installation, operation, and maintenance instructions for the health-care professional trained in monitoring respiratory and cardiovascular activity.

These instructions contain important information for safe use of the product. Read the entire contents of these Instructions For Use, including Warnings and Cautions, before using the monitor. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient.

# **Definition of Symbols**

SYMBOL	DEFINITION
Rx	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
*	Type BF Equipment
$\triangle$	Attention, see instructions for use.
À	Refer servicing to qualified service personnel.
×	This device has no alarms.
%SpO <sub>2</sub>	Percent Oxygen Saturation
<b>♥</b> bpm	Pulse Rate (beats per minute)
PI	Pulse Amplitude Index
(1111	Battery Charge Indicator
⊅-	External Power Indicator
%	On/Off Key
1	Printer LED - Real Time Printout
2	Printer LED - Numeric Trend Tables
3	Printer LED - Graphic Trend
?	Printer LED - Error
	Printer Key - Select Print
	Printer Key - Start / Stop Print
<i>□</i>	Docking Station LED - AC Power
<b>①</b>	Docking Station LED - USB Power
	Docking Station LED - Charging Spare Battery
11.	Printer icon: Small Pulse (WW1020 only)
<b>✓</b>	Printer icon: Check Sensor
<b>#</b> 4	Printer icon: Searching too Long
<b>Ø</b>	Printer icon: Lost Pulse

SYMBOL	DEFINITION	
Mn	Printer icon: Artifact (WW1020 only)	
(2)	Do not reuse. One use on one patient.	
Ø	Moisture Sensitive	
₩	Not suitable for use in the presence of a flammable anesthetic mixture.	
$\hookrightarrow$	Output Voltage Connector	
$\rightarrow$	Input Voltage Connector	
===	Direct Current	
IPX2	Drip proof (monitor and dock only)	
REF	Catalog Number	
	Date of Manufacture	
EC REP	Authorized Representative in the European Community	
Collect Separately	Disposal (EU Countries) Under the Waste Electrical and Electronic Equipment (WEEE) Directive 2006/96/EC and implementing regulations, all devices and service items within the scope of the Directive purchased new after August 13, 2005 must be sent for recycling when ultimately becoming waste. Devices and items must not be disposed of with general waste.  If purchased before that date, they may also be sent for recycling if being replaced on a one-for-one, like-for-like basis (this varies depending on the country). Recycling instructions to customers using Smiths Medical products are published on the internet at: http://www.smiths-medical.com/recycle	
	Disposal (other countries)	
	When disposing of this device, its batteries or any of its accessories, ensure that any negative impact on the environment is minimized. Contact your local waste disposal service and use local recycling or disposal schemes. Separate any other parts of the equipment where arrangements can be made for their recovery; either by recycling or energy recovery. The main batteries are potentially harmful and will require separate disposal according to manufacturer's instructions or local regulations.	
	Note: If applicable, EU, national or local regulations concerning waste disposal must take precedence over the above advice.	

KEYWORD	DEFINITION	
WARNING	Something that could hurt the patient or hurt the operator.	
CAUTION	Something that could damage the monitor.	
NOTE	Other important information.	

#### **Warnings**

WARNING! This device is not intended for continuous patient monitoring. This device is intended to measure the patient's %SpO<sub>2</sub> and pulse rate values. There are no audible or visible alarms.

WARNING! The monitor was not designed or tested to be an apnea monitor.

WARNING! Do not use this device in the presence of flammable anesthetics.

WARNING! Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment.

WARNING! Operation of this device may be adversely affected in the presence of conducted transients or strong electromagnetic (EM) or radiofrequency (RF) sources, such as portable and mobile RF communication equipment, electrosurgery and electrocautery equipment, x-rays, and high intensity infrared radiation.

WARNING! Operation of this device may be adversely affected in the presence of computed tomograph (CT) equipment.

WARNING! Any monitor that has been dropped or damaged should be inspected by qualified service personnel, prior to use, to insure proper operation.

WARNING! If the accuracy of any measurement is in question, verify the patient's vital signs by an alternative method, and then check the monitor for proper functioning.

WARNING! This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment.

WARNING! This device is intended for use by persons trained in professional health care or those who have access to the oversight of a professional health care provider.

The operator must be thoroughly familiar with the information in this manual before using the device.

WARNING! Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

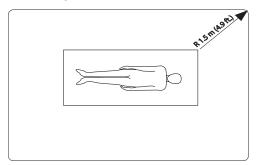
WARNING! When attaching sensors with Microfoam® tape, do not stretch the tape or attach the tape too tightly. Tape applied too tightly may cause inaccurate readings and blisters on the patient's skin (lack of skin respiration, not heat, causes the blisters).

WARNING! Use only SpO<sub>2</sub> sensors supplied with, or specifically intended for use with, this device.

- WARNING! Incorrectly applied sensors may give inaccurate readings. A Refer to the sensor insert for proper application instructions.
- WARNING! Do not autoclave, ethylene oxide sterilize, or immerse the sensors in liquid. This may cause damage to the sensor which may cause inaccurate readings.
- WARNING! Unplug the sensor from the oximeter before cleaning or disinfecting to prevent damaging the sensor or monitor, and to prevent user safety hazards.
- WARNING! Measurements made at sites with low perfusion are potentially inaccurate. Always use measurements in conjunction with other clinical signs and symptoms.
- WARNING! SpO<sub>2</sub> measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.
- WARNING! Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, fluorescein, and patent blue V (PBV) may adversely affect the accuracy of the SpO<sub>2</sub> reading.
- WARNING! Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse rate and SpO<sub>2</sub> readings.
- WARNING! Optical cross-talk can occur when two or more sensors are placed in close proximity. It can be eliminated by covering each site with an opaque material.
- WARNING! Remove fingernail polish or false fingernails before applying SpO<sub>2</sub> sensors. Fingernail polish or false fingernails may cause inaccurate SpO<sub>2</sub> readings.
- WARNING! Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin (with CO-poisoning) or methemoglobin (with sulfonamide therapy), will affect the accuracy of the SpO<sub>2</sub> measurement.
- WARNING! Tissue damage may result from overexposure to sensor light during photodynamic therapy with agents such as verteporphin, porfimer sodium, and metatetrahydroxyphenylchlorin (mTHPC). Change the sensor site at least every hour and observe for signs of tissue damage. More frequent sensor site changes/inspections may be indicated depending upon the photodynamic agent used, agent dose, skin condition, total exposure time or other factors. Use multiple sensor sites.
- WARNING! When connecting this monitor to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. Accessory equipment connected to the monitor's data interface must be certified according to the respective IEC standards, i.e., IEC 60950 for data processing equipment or IEC 60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC 60601-1-1 systems requirements. Anyone connecting additional equipment to the signal input port or the signal output port configures a medical system, and therefore is responsible that the system complies with the requirements of the system standard IEC 60601-1-1.

WARNING! IEC 60950 approved equipment must be placed outside the "patient environment." The patient environment is defined as an area 1.5 m (4.92 feet) from the patient.

Figure 1-1: Patient Environment



- WARNING! The oximeter will not operate without batteries installed. Properly charged batteries provide a reserve source of power in case of external power failure. Never use an oximeter with discharged batteries to monitor a patient.
- WARNING! Inspect battery terminals for corrosion or contamination. The monitor may not operate properly if battery terminals are corroded or contaminated. Do not use until battery terminals have been properly cleaned and repaired.
- WARNING! Check expiration date of batteries. The monitor may not operate properly if expired batteries are used. Do not use until proper batteries can be obtained.
- WARNING! Remove device batteries prior to long term storage.
- WARNING! Do not allow the patient to handle the device if the battery door has been removed, except while installing new batteries.
- WARNING! Disconnect the external power supply from the monitor or Docking Station before disinfecting or cleaning the monitor.
- WARNING! Do not plug the monitor or Docking Station into an outlet controlled by a wall switch.
- WARNING! Disconnect the AC power supply from the outlet before disconnecting it from the monitor. Leaving the AC power supply connected to an AC power outlet without being connected to the monitor may result in a safety hazard.
- WARNING! Do not allow any moisture to contact the AC power supply connectors, or a safety hazard may result. Ensure that hands are thoroughly dry before handling the AC power supply.
- WARNING! Do not place the monitor or Docking Station in the patient's bed or crib. Do not place the monitor or Docking Station on the floor.
- WARNING! Failure to place the monitor or Docking Station away from the patient may allow the patient to turn off, reset, or damage the monitor, possibly resulting in the patient not being monitored. Make sure the patient cannot reach the monitor from their bed or crib.

#### Chapter 1: Introduction

- WARNING! Failure to carefully route the cable from the sensor to the monitor may allow the patient to become entangled in the cable, possibly resulting in patient strangulation. Route the cable in a way that will prevent the patient from becoming entangled in the cable. If necessary, use tape to secure the cable.
- WARNING! If there is a risk of the AC power supply becoming disconnected from the monitor during use, secure the cord to the monitor several inches from the connection.
- WARNING! Ensure the device's AC rating is correct for the AC voltage at your installation site before using this monitor. The monitor's AC rating is shown on the external power supply. If the rating is not correct, do not use the monitor. Contact the Smiths Medical PM, Inc. service department, or your authorized service representative, for help.
- WARNING! Use only the power supply included with your monitor, or approved by Smiths Medical PM, Inc. Use of an inappropriate power supply may cause a patient shock hazard or cause the oximeter to stop monitoring. See *Chapter 10:*Optional Supplies & Accessories, for additional specific information.
- WARNING! The Docking Station must have a Printer or Printer Port Cover installed. Failure to do so may cause a risk of electrical shock to the patient or operator or risk damage to the equipment.
- WARNING! Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO<sub>2</sub> and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

WARNING! Verify that all LEDs (light emitting diodes) on the display light up upon startup of the device.

#### **Cautions**

- CAUTION! Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- CAUTION! A Do not disassemble unit, not user serviceable. Refer to qualified service personnel.
- CAUTION! Failure to charge the monitor while the monitor is in long term storage may shorten the battery life. Charge the monitor while it is in storage to ensure the longest battery life.
- CAUTION! Due to limitations of the Li-lon chemistry, the rechargeable battery pack should not be charged at ambient temperatures above 45 °C (113 °F) or below 5 °C (41 °F).
- CAUTION! The WW1090 rechargeable battery pack is shipped with only 30% of full charge.

  The battery pack must be charged completely before use.
- CAUTION! The WW1090 rechargeable battery pack utilizes Li-lon secondary cells. Dispose of spent batteries in compliance with your institution's guidelines and local ordinances.
- CAUTION! Observe proper battery polarity (direction) when replacing batteries.
- CAUTION! Do not allow water or any other liquid to spill onto the monitor or Docking Station. Do not autoclave, ethylene oxide sterilize, or immerse the monitor or Docking Station in liquid. Evidence that liquid has been allowed to enter the monitor or Docking Station voids the warranty.
- CAUTION! Where the equipment has accidentally gotten wet, it should be wiped dry externally and allowed to dry thoroughly before use.
- CAUTION! Before cleaning or disinfecting the printer, unplug the AC adapter, remove the batteries and remove the paper.
- CAUTION! Do not allow printer paper to become wet. If the printer paper gets wet, remove the paper immediately. Do not use the printer until the paper is replaced.
- CAUTION! Chemicals used in some cleaning agents may cause brittleness of plastic parts. Follow cleaning instructions in this manual.
- CAUTION! Cleaning with disinfectants, including alcohol, may shorten the life of the plastic or electronic parts, but appropriate disinfection must still be performed.
- CAUTION! Pressing any key with sharp or pointed instruments may permanently damage the keypad. Only press keys with your finger.

#### **Notes**

- NOTE: The WW1090 rechargeable battery pack utilizes circuitry that optimizes the charging of the batteries. New packs will require multiple charge / discharge learning cycles before optimum performance is obtained.
- NOTE: "SpO<sub>2</sub> averaging" means the number of pulse beats over which the SpO<sub>2</sub> value is averaged; "pulse averaging" means the number of seconds over which the pulse value is averaged.
- NOTE: Increasing or decreasing the averaging setting has no effect on the data update rate.
- NOTE: A Patient Simulator does not calibrate the monitor. The monitor does not require calibration. A Patient Simulator provides a known SpO<sub>2</sub> and pulse rate to the monitor that allows the monitor's performance to be checked.
- NOTE: A Patient Simulator cannot be used to assess the accuracy of a pulse oximeter and/or sensor.

# **Chapter 2: Intended Use and Monitor Features**

#### Intended Use for the WW1020 Oximeter

The BCI® WW1020 pulse oximeter is intended for spot-checking applications (non continuous use). It monitors and displays patient's functional oxygen saturation (%SpO<sub>2</sub>), pulse rate (♥bpm), pulse signal strength, and pulse amplitude index (PI) readings. It may be used by physicians, respiratory therapists, nurses, certified nurse assistants, emergency medical technicians, sleep technicians, and home users. The intended patient population ranges from neonatal to adult. It may be used on patients with low perfusion or during patient motion. The WW1020 may be used in the hospital or clinical environment, during emergency land transport, and in the home.

WARNING! The monitor was not designed or tested to be an apnea monitor.

#### Intended Use for the WW1000 Oximeter

The BCI® WW1000 pulse oximeter is intended to be used for spot-checking (non-continuous use). It monitors and displays a patient's functional oxygen saturation (%SpO<sub>2</sub>), pulse rate (♥bpm), pulse signal strength, and pulse amplitude index (PI) readings. It may be used by physicians, respiratory therapists, nurses, certified nurse assistants, emergency medical technicians, sleep technicians, clinicians, and home users. The intended patient population ranges from infant to adult. It can be used on patients with low perfusion. The WW1000 may be used in the hospital or clinical environment, during emergency land transport, and in the home.

WARNING! The monitor was not designed or tested to be an apnea monitor.

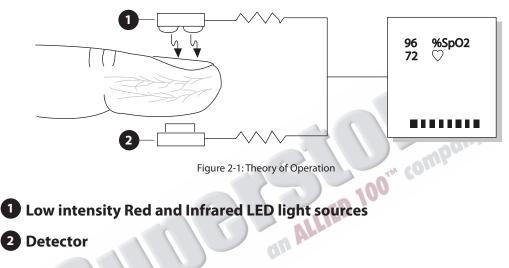
#### **Monitor Features**

- Provides fast, reliable SpO<sub>2</sub>, pulse rate, and pulse signal strength measurements on any patient, from neonate to adult for the WW1020 or from small infant to adult for the WW1000.
- Maintains accurate readings during periods of patient motion (WW1020 only) and when monitoring patients with low perfusion.
- Ideally suited for use in hospitals, outpatient clinics, emergency rooms, during emergency land transport, in sleep labs, or in-home use.
- Portable and lightweight. Weighs only 330 grams (12 ounces), with 4"AA" batteries.
- On-board sensor storage cradle holds the finger sensor when not in use.
- Power options include four (4) standard "AA" (type IEC LR6) alkaline batteries, a rechargeable Lithium Ion battery pack, USB power, or an AC power adapter.
- Rechargeable battery life for a new battery is approximately thirty-one (31) hours for the WW1020, fifty-four (54) hours for the WW1000.
- · An easy to read battery gauge indicates the charge level and provides a low battery alert.
- Large, bright, easy-to-read LED display indicates SpO<sub>2</sub> and pulse rate measurements.
- 2 Nine-segment LED bar graphs indicate pulse signal strength and pulse amplitude index.
- Optional docking station transforms the device into a table top pulse oximeter, and can also be used to recharge the monitor's lithium lon battery pack, and a spare battery pack.
- Optional printer allows for printing of trend information or real time data logs.

# **Theory of Operation**

The pulse oximeter determines %SpO<sub>2</sub> and pulse rate by passing two wavelengths of low intensity light, one red and one infrared, through body tissue to a photodetector. Information about wavelength range can be especially useful to clinicians. Wavelength information for this device can be found in the SpO<sub>2</sub> Specifications section of this manual.

Pulse identification is accomplished by using plethysmographic techniques, and oxygen saturation measurements are determined using spectrophotometric oximetry principles. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the sensor placement, the intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissues.



The oximeter processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and  $SpO_2$ ) to identify the pulses and calculate functional oxygen saturation. Oxygen saturation calculations can be performed because blood saturated with oxygen predictably absorbs less red light than oxygen-depleted blood.

WARNING! Since measurement of SpO<sub>2</sub> depends on a pulsating vascular bed, any condition that restricts blood flow, such as the use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate SpO<sub>2</sub> and pulse rate readings.

WARNING! Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO<sub>2</sub> and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

#### **Pulse Amplitude Index**

The PI value is a relative measure of pulse-signal strength over time at a pulse oximeter monitoring site, and is non-pulsatile in nature. Pulse Amplitude Index is defined as PI = (100 \* AC)/DC where AC is the alternating current (pulsatile component of the signal) and DC is direct current (non-pulsatile component of the signal). For more information, see *Pulse Amplitude Index* in *Chapter 4: Operating Instructions*.

NOTE! The PI value is a relative value that varies from patient to patient.

# Patented Technology (WW1020 only)

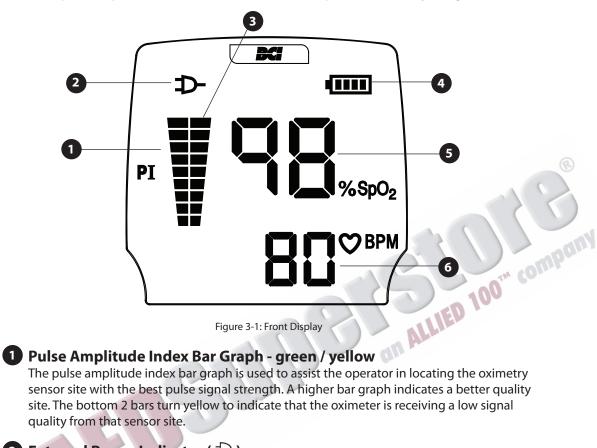
This oximeter incorporates patented technology and noise reducing hardware to enhance the oximeter's ability to detect pulse amplitude in patients with poor peripheral perfusion. Blood Pulse Detection Method Using Serial Autocorrelation (SAC), patent number 5,558,096, analyzes a digitized signal, in real time, and compares it with previous pulse data. If similar characteristics to previous data are recognized, the device confirms a valid pulse. In essence, an individual's pulse data is retained and used as a template to accept or reject future pulse signals. Patented technology, digital signal processing, and a greatly improved signal to noise ratio, provide for improved performance.

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# **Chapter 3: Controls and Features**

# **Front Display**

The display shows the measurements for SpO<sub>2</sub> and Pulse Rate. It also shows a pulse strength indicator, a pulse amplitude indicator and indicators for AC power and battery charge level.



2 External Power Indicator ( 🗘 ) - green

This indicator is lit when the device is receiving power from the AC adapter or USB cable.

3 Pulse Signal Strength Bar Graph - red

The pulse strength bar graph "sweeps" with the patient's pulse beat. The height of the bar graph is a logarithmic representation of the pulse signal strength.

4 Battery Charge Indicator - green (yellow if low)

The battery charge indicator shows the current state of charge of the installed battery. LED segments will disappear as the battery becomes weaker. When only one LED is lit and flashing yellow, the batteries will expire within minutes; replace the batteries.

NOTE! This indicator is OFF if AA batteries are installed and  $\bigcirc$  is illuminated.

5 SpO<sub>2</sub> Numeric Display - red

A number shows the patient's functional oxygen saturation value in percent. Dashes (--) indicate the monitor is not able to calculate the SpO<sub>2</sub> value.

6 Pulse Rate Numeric Display - red

A number shows the patient's pulse rate value in beats per minute. Dashes (---) indicate the monitor is not able to calculate the pulse rate value.

# **Monitor Operating Key**

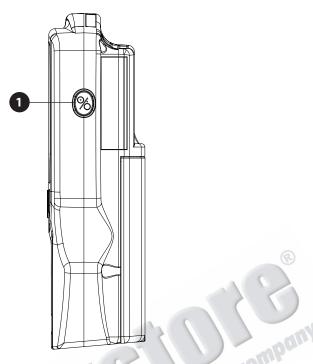


Figure 3-2: Monitor Operating Key

# 1 % ON/OFF Key

Momentarily press this key when the device is OFF to turn the monitor ON. Press this key when the device is ON to turn the monitor OFF.

Press and hold this key when the device is OFF to clear the patient trend data.

#### **Monitor Back and Bottom Panels**

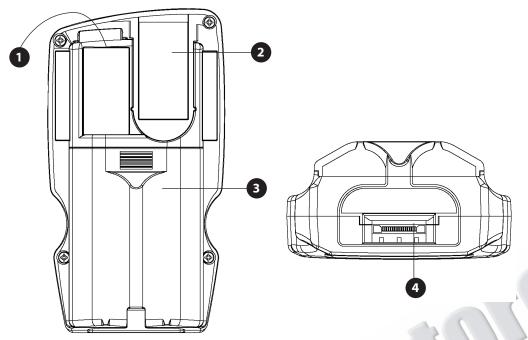


Figure 3-3: Monitor Back and Bottom Panels

1 Sensor / RS232 Connector

The sensor or an extension cable attaches here. With the sensor removed, trend data can be downloaded from this connector using an RS232 serial interface cable. See *Chapter 7*: *Connecting to a PC* for details.

2 Sensor Storage Slot

Reusable BCI<sup>®</sup> sensors can be securely stored here when not in use by using a WW1080 Sensor Cradle.

**3** Battery Compartment

This compartment holds the disposable batteries or the rechargeable battery pack.

4 Data Input/Output or Power Input Connector

This connector can accept the AC power adapter or the USB cable. The docking station uses this connector for both power and data.

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# **Chapter 4: Operating Instructions**

# **Unpacking the Monitor**

The following items are shipped with the oximeter:

- Monitor
- Three (3) sensor cradles (WW1080)
- Spot check sensor (3044S)
- Four (4) "AA" (LR6) alkaline batteries
- · Operation manual
- Service manual (CD)

Carefully remove the monitor and its accessories from the shipping carton. Save the packing materials in case the monitor must be shipped or stored. Compare the packing list with the supplies and equipment received.

# **Powering the Oximeter**

The oximeter will operate from battery power or from external power with battery back up. The optional WW1095 (30 Watt) AC power supply may be used to provide power to the oximeter. The AC power supply is required when utilizing the docking station to ensure the proper operation of the docking station with all accessories, including auxiliary battery charger and optional printer.

WARNING! The WW1020/WW1000 will not operate without batteries installed. Properly charged batteries provide a reserve source of power in case of external power failure. Never use an oximeter with discharged batteries to monitor a patient, as the monitor may not operate properly in the case of external power failure.

The oximeter can obtain external power in the following ways:

- The oximeter can be placed in its docking station. See *Chapter 6: Optional Docking Station and Printer*.
- The AC power supply can be plugged directly into the oximeter (Figure 4-3).
- The AC power supply can be plugged into the WW1089 USB Interface Cable (Figure 4-4).
- The oximeter can be powered by a PC through the USB Interface cable (Figure 4-5).

After connecting to power, verify that the green External Power Indicator is lit.

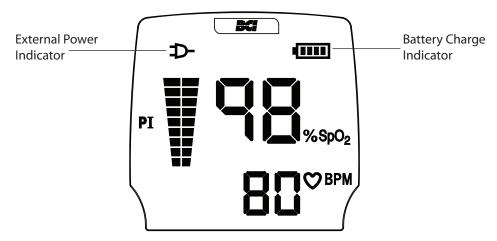


Figure 4-1: External Power/Charge Indicators

If an AC source is present, the oximeter will draw power from it first. While the oximeter is operating from an AC source, the External Power Indicator ( $\mathfrak{D}$ -) will illuminate.

If there is enough power, the WW1090 Lithium-Ion (LI+) rechargeable battery pack will also charge, if installed. The battery charge indicator ( ••••••) will display segments showing the charge level. As the battery charges, more green segments will light, until all four are lit.

#### NOTE: The AC Power supply does NOT charge "AA" (LR6) alkaline batteries.

If no external power source is available, the oximeter will draw battery power. When the battery charge is low enough, the Battery Indicator shows one yellow segment. When the battery has less than approximately 10 minutes of charge left, that segment will flash.

If no AC source is available, the oximeter will operate from an external USB source only when attached to a WW1089 USB Interface Cable and energized USB connection. In this case, the external power indicator lights. If enough power is available, the optional WW1090 Lithium-Ion (Li+) rechargeable battery pack will trickle charge.

# **Installing the Batteries**

The oximeter uses four (4) standard "AA" alkaline, IEC Type LR6, cells (Figure 4-2A) or a custom rechargeable Lithium-lon (Li+) battery pack (WW1090 - Figure 4-2B).

WARNING! Inspect battery terminals for corrosion or contamination. The monitor may not operate properly if battery terminals are corroded or contaminated. Do not use until battery terminals have been properly cleaned and repaired.

WARNING! Check the expiration date for the batteries. The monitor may not operate properly if expired batteries are used. Do not use until proper batteries can be obtained.

WARNING! Remove the batteries prior to long term storage.

WARNING! Do not allow the patient to handle the device if the battery door has been removed, except while installing new batteries.

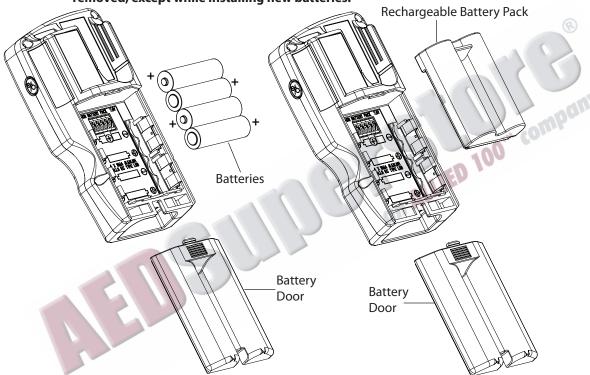


Figure 4-2A: AA (LR6) Alkaline Battery Placement

Figure 4-2B: Rechargeable Lithium-Ion Battery Pack

#### To install/replace the batteries:

- 1. Depress the battery door tab near the center of the oximeter and slide the cover off toward the bottom of the monitor.
- 2a. If using "AA" (LR6) alkaline batteries: Install the negative end of each battery first, compressing the battery terminal spring until the positive terminal clears the positive tab. Press the battery down into place.

# NOTE: Dispose of spent batteries in compliance with your institution's guidelines and local ordinances.

- 2b. If using WW1090 Li-lon (Li+) rechargeable battery pack: Align the battery pack so that the metal connectors line up with the connectors in the WW1020/WW1000 battery compartment. Push the WW1090 Lithium-lon (Li+) rechargeable battery pack straight in to place.
- 3. Replace the battery door by sliding the cover back until the latch clicks.

- CAUTION! Due to limitations of the Li-lon chemistry, the rechargeable battery pack should not be charged at ambient temperatures above 45 °C (113 °F) or below 5 °C (41 °F)
- CAUTION! The WW1090 rechargeable battery pack is shipped with only 30% of full charge.

  The battery pack must be charged completely before use.
- CAUTION! The WW1090 rechargeable battery pack utilizes Li-lon secondary cells. Dispose of spent batteries in compliance with your institution's guidelines and local ordinances.
- NOTE: The WW1090 rechargeable battery pack utilizes circuitry that optimizes the charging of the batteries. New packs will require multiple charge / discharge learning cycles before optimum performance is obtained.
- NOTE: The rechargeable battery can be charged in the oximeter or in the spare bay of the WW1025 Docking Station. The WW1095 AC power supply is required for charging, and can be used with both the oximeter and the Docking Station.

#### **External Power**

- WARNING! Disconnect the external power supply from the monitor before disinfecting or cleaning the monitor.
- WARNING! Do not plug the monitor into an outlet controlled by a wall switch.
- WARNING! Do not allow any moisture to contact the AC power supply connectors, or a safety hazard may result. Ensure that hands are thoroughly dry before handling the AC power supply.
- WARNING! Do not place the monitor in the patient's bed or crib. Do not place the monitor on the floor.
- WARNING! Failure to place the monitor away from the patient may allow the patient to turn off, reset, or damage the monitor, possibly resulting in the patient not being monitored. Make sure the patient cannot reach the monitor from their bed or crib.
- WARNING! Failure to carefully route the cable from the sensor to the monitor may allow the patient to become entangled in the cable, possibly resulting in patient strangulation. Route the cable in a way that will prevent the patient from becoming entangled in the cable. If necessary, use tape to secure the cable.
- WARNING! If there is a risk of the AC power supply becoming disconnected from the monitor during use, secure the cord to the monitor several inches from the connection.
- WARNING! Patient safety can be compromised by the use of a power supply not supplied by Smiths Medical PM, Inc. Use only the power supply included with your monitor, or one approved by Smiths Medical PM, Inc.
- WARNING! Ensure the device's AC rating is correct for the AC voltage at your installation site before using this monitor. The monitor's AC rating is shown on the external power supply. If the rating is not correct, do not use the monitor. Contact the Smiths Medical PM, Inc. service department, or your authorized service representative, for help.

#### **AC Power**

The AC power supply can plug into the oximeter (Figure 4-3) or into the WW1089 USB interface

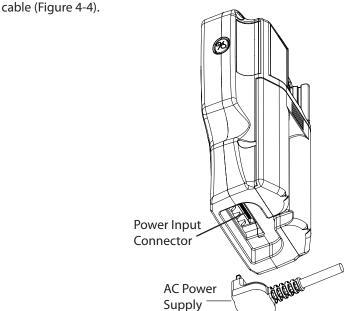
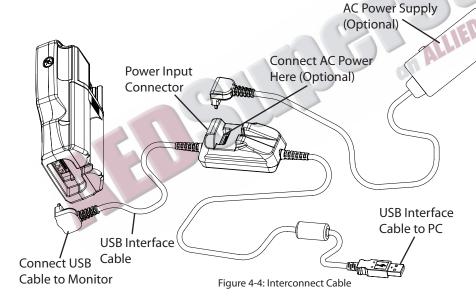


Figure 4-3: AC Power Supply



Refer to *Chapter 10: Optional Supplies & Accessories* to verify the proper AC power supply for your application. The following power supplies are suitable for use with this monitor:

CAT. NUMBER	OUTPUT POWER	INPUT POWER
WW1095	30 W	AC power supply 100-240 VAC 50 - 60Hz

WARNING! Only use a power supply intended for use with this monitor. Use of an inappropriate power supply may cause a patient shock hazard or cause the oximeter to stop monitoring.

CAUTION! Use only the interconnect cables specifically intended for use with this device. See *Chapter 10: Optional Supplies & Accessories*, for ordering information.

#### **USB Power (Universal Serial Bus)**

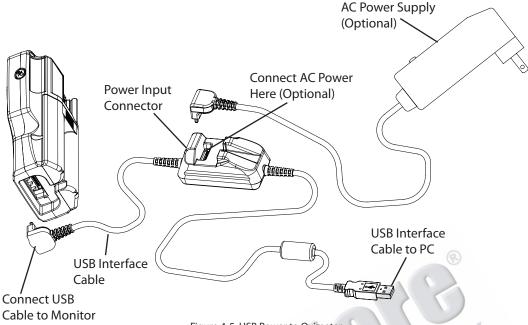


Figure 4-5: USB Power to Oximeter

The oximeter may be powered from an external USB source such as a laptop computer or powered USB hub. The WW1089 USB Interface Cable is a custom cable used to connect the oximeter or docking station to an external computer via its USB port. See *Chapter 7: Connecting to a PC* for more information. This port can supply a source of operating power to the oximeter.

NOTE! The WW1090 Lithium-lon (Li+) Rechargeable Battery Pack can be fast charged by installing it in the oximeter and supplying power, using the AC Power Supply either directly or through the Docking Station. The WW1090 Li+ Rechargeable Battery Pack can also be fast charged by installing it directly in the Docking Station and supplying power using the AC Power Supply.

NOTE: To slow charge the WW1090 Lithium-Ion (Li+) Rechargeable Battery Pack, install the Battery Pack in the oximeter and connect to USB power. Slow charging may take 20 hours or more. USB power cannot charge the spare Li+ Rechargeable Battery Pack in the Docking Station.

# **Turning On the Monitor**

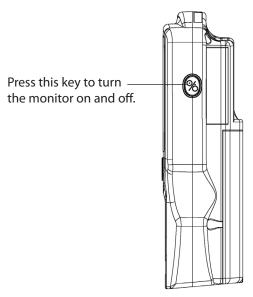


Figure 4-6: Turning On the Monitor

To turn on the monitor, press the % key. Before using the monitor, check the following at power-up:

- · All LEDs light.
- The monitor's software revisions (main, battery PIC, oximeter) are momentarily displayed.
- · The patient record number is momentarily displayed.

After a few seconds the % SpO<sub>2</sub> value, pulse rate, pulse signal strength and PI bar graphs should be shown. If not, see *Chapter 9: Troubleshooting* for help.

# WARNING! Verify that all LEDs (light emitting diodes) on the display light up upon startup of the device.

If the oximeter detects an error during power up, " $\mathbf{E}_{\Gamma \Gamma}$ " will display in the pulse rate section of the display. A numeric error code will display in the SpO<sub>2</sub> section. See *Chapter 9: Troubleshooting* for more information.

# **Checking the Monitor's Configuration**

While turning the monitor on, hold the % key until  $\llbracket L \varGamma \rrbracket$  starts to flash, then release the key while  $\llbracket L \varGamma \rrbracket$  is flashing to see a list of configuration settings.

NOTE! If the % key is held for about 15 seconds or more, [ ] r will stop flashing and TREND DATA WILL BE CLEARED!

Configuration settings are:

- Auto Shutoff ( \$\frac{1}{15}\$), default = no;
- LED Brightness ( db), default = 8 (of 10);
- Trend Interval ( 5E ), default = 4 seconds;
- Oximeter High Sensitivity ( **\( \mathcal{H5} \)**) WW1020 only, default = off
- Oximeter Averaging ( \( \begin{aligned} \Pi \lefta \righta \
- Language ( **∠ 月** ⊓) User selectable

While the language setting is displayed, successive % key presses will cycle through the language selections:

- English ( **E** ∩) default
- French / Français ( Fr)
- German / Deutsch ( 戌 €)
- Spanish / Español ( £5)
- Italian / Italiano ( 🎉 )
- ・ Continental Portuguese / Português (**アと**)
- ・ Brazilian Portuguese / Português Brasil ( 占 r)
- Swedish / Svenska ( 5d)
- Dutch / Nederlands ( n L )

Stop pressing the key when the desired language is selected. After five (5) seconds, normal monitoring mode resumes.

# **Checking the Monitor's Performance**

Pulse oximeters do not require user calibration. If checking the function of the device is desired, an Oximetry Patient Simulator (Smiths Medical PM, Inc. catalog number 1606) is available as an accessory. The simulator attaches to the oximeter in place of the sensor. It provides a known  ${\rm SpO}_2$  and pulse rate signal to the oximeter.

NOTE: A Patient Simulator does not calibrate the monitor. The monitor does not require calibration. A Patient Simulator provides a known SpO<sub>2</sub> value and pulse rate to the monitor that allows the monitor's performance to be checked.

NOTE: A Patient Simulator cannot be used to assess the accuracy of a pulse oximeter and/ or sensor.

# **Attaching the Sensor to the Patient**

To attach the sensor to the patient:

- 1. Choose the appropriate sensor. See sensor table for additional information.
- 2. If using a reusable sensor, clean or disinfect the sensor per *Cleaning or Disinfecting the Sensors* section in this chapter. ( Disposable sensors are for single-patient use and do not require cleaning or disinfecting.)
- 3. Check the sensor and oximetry cable for damage and integrity. See *Checking the Sensor and Oximetry Cable* section for additional information.
- 4. Attach sensor to the patient.
- WARNING! Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.
- WARNING! When attaching sensors with Microfoam® tape, do not stretch the tape or attach the tape too tightly. Tape applied too tightly may cause inaccurate readings and blisters on the patient's skin (lack of skin respiration, not heat, causes the blisters).
- WARNING! SpO<sub>2</sub> measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.
- WARNING! Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein, may adversely affect the accuracy of the SpO<sub>2</sub> reading.
- WARNING! Optical cross-talk can occur when two or more sensors are placed in close proximity. It can be eliminated by covering each site with an opaque material.
- WARNING! Remove fingernail polish or false fingernails before applying SpO<sub>2</sub> sensors. Fingernail polish or false fingernails may cause inaccurate SpO<sub>2</sub> readings.
- WARNING! Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin (with CO-poisoning) or methemoglobin (with sulfonamide therapy), will affect the accuracy of the SpO<sub>2</sub> measurement.
- WARNING! Tissue damage may result from overexposure to sensor light during photodynamic therapy with agents such as verteporphin, porfimer sodium, and metatetrahydroxyphenylchlorin (mTHPC). Change the sensor site at least every hour and observe for signs of tissue damage. More frequent sensor site changes/inspections may be indicated depending upon the photodynamic agent used, agent dose, skin condition, total exposure time or other factors. Use multiple sensor sites.

# **Choosing the Sensor**

WARNING! Use only SpO<sub>2</sub> sensors and cables supplied with, or specifically intended for use with, this BCI® oximeter. Use of sensors not intended for use with this device may cause inaccurate readings.

WARNING! Incorrectly applied sensors may give inaccurate readings. <u>N</u> Refer to the sensor insert for proper application instructions.

Choose the appropriate sensor from the following chart. Select the sensor based on the patient's size, available application site, attachment method and other pertinent clinical information.

 $\underline{\wedge}$  See the sensor's instruction insert for detailed attachment methods and other important information.

#### **BCI® Sensors**

PATIENT	SITE	DESCRIPTION
Adult over 45 kg	Finger	3044: Sensor, Reusable, Adult 3044S: Spot Check Sensor, Reusable, Adult 3444: Sensor, Reusable, Comfort Clip®
	Finger or Toe	3043: Sensor, Reusable, Universal 'Y' 1300: Sensor, Disposable, Adult Finger
	Ear	WW3078: Sensor, Reusable, Ear
Pediatric 15-45 kg	Finger Finger or Toe	3044: Sensor, Reusable, Adult (>20 kg) 3044S: Spot Check Sensor, Reusable, Adult 3444: Sensor, Reusable, Comfort Clip <sup>®</sup> 3178: Sensor, Reusable, Pediatric Finger (5-45 kg) 3178S: Spot Check Sensor, Reusable, Pediatric
	Ear	3043: Sensor, Reusable, Universal 'Y' 1301: Sensor, Disposable, Pediatric Finger  WW3078: Sensor, Reusable, Ear
Infant	Hand or Foot	3043: Sensor, Reusable, Universal 'Y'
3-15 kg	Toe	3025: Sensor, Reusable, Wrap, Infant
	Finger or Toe	1303: Sensor, Disposable, Infant (2)
All	Extension Cable	3311: Cable, Oximetry 1.5 meters (5 feet)
NEONATE SENSORS	FOR THE WW1020	ONLY
Neonate under 3 kg	Hand or Foot	1302: Sensor, Disposable, Neonate/Small Infant (2)
	Foot	3026: Sensor, Reusable, Wrap, Neonate/Small Infant
SMALL INFANT SENS	SORS FOR THE WW	1000 ONLY
Small Infant * under 3 kg	Hand or Foot	1302: Sensor, Neonate/Small Infant (disposable)
	Foot	3026: Sensor, Wrap, Neonate/Small Infant (reusable)
*The BCI® 1302 and 302	26 oximetry sensors sl	hould not be used on neonatal patients with the

WW1000 monitor. Testing has not been conducted for the WW1000 for patients less than 30 days

old. These sensors may, however be used on older patients.

#### **Nellcor® Sensor (WW1020 Only)**

PATIENT	SITE	DESCRIPTION
Adult over 45 kg	Finger	DS100A finger sensor (reusable)

# Cleaning or Disinfecting the Sensors

Clean or disinfect reusable sensors before attaching to a new patient.

WARNING! Unplug the sensor from the monitor before cleaning or disinfecting.

WARNING! Do not autoclave, ethylene oxide sterilize, or immerse the sensors in liquid.

Clean the sensor with a soft cloth moistened in water or a mild soap solution. To disinfect the sensor, wipe the sensor with a 70% isopropyl alcohol solution. If there is contamination with blood borne pathogens (BBPs) or other potentially infectious materials (OPIMs), then the use of a facility approved disinfectant of appropriate spectrum for the suspected organisms is appropriate.

CAUTION! Do not immerse the sensor in any liquid.

CAUTION! Cleaning with disinfectants, including alcohol, may shorten the life of the plastic or electronic parts, but appropriate disinfection must still be performed. LLIED 100

# **Checking the Sensor and Oximetry Cable**

Follow these instructions each time before you attach the sensor to the patient. This helps ensure the sensor and oximetry cable are working properly.

- WARNING! Using a damaged oximetry sensor or cable may cause inaccurate readings. Inspect each sensor and cable. If a sensor or cable appears damaged, do not use it. Use another sensor or cable or contact your authorized service representative for help.
- WARNING! Do not use more than one Oximetry Extension Cable. The monitor may fail to operate properly if multiple Oximetry Extension Cables are connected together.

WARNING! Misuse or improper handling of the sensor and cable may result in damage to the sensor. This may cause inaccurate readings.

- 1. Before the sensor is attached, check the integrity of the sensor and cable.
- 2. If not using the oximetry extension cable, connect the sensor to the oximeter. Push the sensor's connector firmly into the oximeter.
  - If using the oximetry extension cable, connect the sensor to the cable and the cable to the oximeter. Push the cable connector firmly into the oximeter.
- 3. Make sure the red light in the sensor is illuminated.
- 4. Now the sensor can be attached to the patient.

WARNING! If any of the integrity checks fail, do not attempt to monitor the patient. Use another sensor or oximetry extension cable, or contact the authorized service representative for help if necessary.

NOTE: Obstructions or dirt on the sensor's red light or detector may cause checks to fail. Make sure there are no obstructions and the sensor is clean.

Hold the connector rather than the cable when connecting or disconnecting the finger sensor to the device.

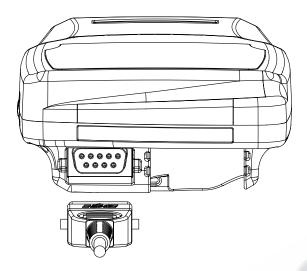


Figure 4-7: Disconnecting or Connecting the Finger Sensor to the Device

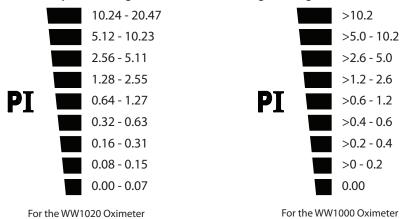
Do not use excessive force or unnecessary twisting when connecting, disconnecting, storing, or when using the sensor. " compe

# **Pulse Amplitude Index**

The Pulse Amplitude Index (PI) bar graph can be useful in assessing the relative quality of the chosen sensor site. The PI value is a relative measure of pulse-signal strength over time at a pulse oximeter monitoring site, and is non-pulsatile in nature. Pulse Amplitude Index is defined as PI = (100 \* AC)/DC where AC is the alternating current (pulsatile component of the signal) and DC is direct current (non-pulsatile component of the signal).

The PI value is represented as a 9-segment bar graph. The more bars lit, the higher the PI value, and generally the better the sensor site. If only the first one or two segments are lit, the segment color changes to yellow, indicating a technical alert condition. This indicates that the oximeter is receiving a low signal quality from that sensor site, and further degradation of the signal quality could cause the oximeter to lose its ability to obtain readings. A different sensor site should be considered.

The PI value approximately maps to a 9-segment bar graph as shown below. The two lowest bars (1 and 2) are bi-color (yellow and green), and bars 3 through 9 are green.



NOTE! The PI value is a relative value that varies from patient to patient.

When placing the sensor on the patient, allow the cable to lay across the top of the hand and parallel to the arm of the patient as shown in Figure 4-8.

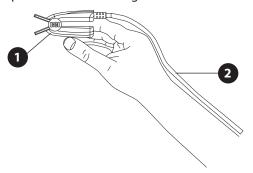


Figure 4-8: Positioning the Cable of the Finger Sensor

Alleo 100" company

- 1 Sensor (finger sensor shown for illustration only)
- 2 Cable



# **Storing the Sensor**

Upon completion of patient monitoring, detach the sensor and loosely coil the finger sensor cable. Store the sensor in the Sensor Storage cradle or other safe place when not in use. Use the proper cradle. Three different sensor cradles are available for this oximeter.

CRADLE	SENSOR TYPE	
1	Should be used for BCI® pediatric size finger sensors	
2	Should be used for the 3444 Comfort Clip® sensor	
3	Should be used for the BCI® adult size finger sensors	

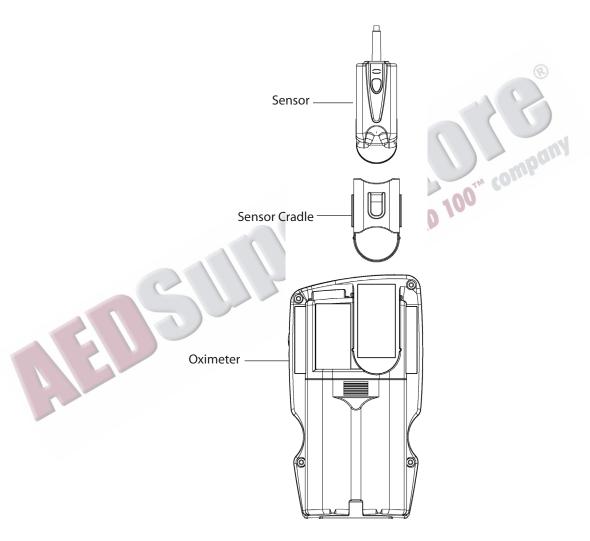


Figure 4-9: Attaching the Sensor and Sensor Cradle to the Monitor

## **Home Use**

WARNING! This device is intended for use by persons trained in professional health care or those who have access to the oversight of a professional health care provider.

The operator must be thoroughly familiar with the information in this manual before using the device.

# **Equipment and Supplies Checklist for Home Use**

Provide the following to the home use caregiver:

QUANTITY	CAT. NO.	DESCRIPTION	
1	WW1020 or WW1000	Oximeter with AA batteries	
1	WW1095	Universal AC mains adapter - 30W	
1	WW1025	Docking Station (optional)	
1	WW1090	Li-lon rechargeable battery pack (optional)	
1	3311 Oximeter Cable, 1.5 meters (5 feet)		
*	* Oximetry Sensor		
*	* Oximetry Sensor Attachments		
1	31169B88	WW1020 / WW1000 Home Use Guide	

<sup>\*</sup> Note: The doctor will prescribe the type and quantity of the sensors needed for homeuse. Be sure that the proper type and quantity of sensor attachments are also prescribed.

The home use caregiver will also need these supplies and reference materials:

QUANTITY	DESCRIPTION	
1	Scissors (for trimming adhesive strips or adhesive tape).	
*	Appropriate disinfectant and a soft, clean cloth (or alcohol wipes) for disinfecting monitor, accessories and reusable sensor.	
1	Emergency phone numbers for the doctor.	
1	Emergency phone number for the hospital emergency room.	
1	Phone number for equipment supplier.	
* Quantity prescribed by doctor.		

### **Training the Home Use Caregiver**

The home use caregiver must be trained in CPR. Inform the caregiver that the oximeter is not to be used as an apnea monitor and should only be used for spot checking applications (non-continuous use). Following this guide while teaching these tasks may help the instructor and the caregiver.

Show the home use caregiver how to:

- Connect the AC Power Supply to a wall outlet.
- Make sure the AC Power Supply outlet is not controlled by a wall switch.
- Connect AC Power Supply to the docking station or oximeter.
- Make sure the monitor's POWER indicator is lit.
- · Visually inspect the sensor and oximetry cable.
- · Connect the sensor to the oximetry cable.
- · Connect the oximetry cable to the monitor.
- · Turn on the monitor.
- · Perform a pre-use check: Verify all display LEDs turn on at power up.
- Route the cable safely from the patient to the monitor to prevent possible patient strangulation.
- Attach the sensor(s) prescribed by the doctor.
- Measure the SpO<sub>2</sub>, pulse rate, PI and pulse signal strength bar graph readings.
- · Interpret the Low Battery Signal.
- Turn off the monitor if appropriate.

### Tell the caregiver how to respond:

- In case of a patient emergency, including what therapy to provide the patient.
- In case the Low Battery Indicator appears.
- In case the caregiver has trouble operating the equipment.

# **Chapter 5: Patient Record Number and Trend Data**

# Description

Whenever the WW1020/WW1000 is monitoring a patient, it stores an  $SpO_2$ , a pulse rate, and PI reading along with any applicable condition flags and a time stamp every four (4) seconds. The stored readings are called trend data. The monitor can store at least 144 hours of trend data for a combination of all 99 available patient record numbers.

# **Incrementing the Patient Record Number**

Each time the monitor is turned on, the patient record number is displayed during the power-up sequence. If valid trend data was collected from the previous patient, the patient record number is incremented at power up. If no valid trend data was collected from the previous patient, the patient record number is not incremented. For example, if the last time the oximeter was on it displayed patient 10 (P  $\bigcirc$  ), the next time it will be P  $\bigcirc$  1, provided that at least one trend data point was saved for P  $\bigcirc$  1. Clearing the trend data resets the patient record number to P 1. See Clearing Trend Data section in this chapter for information on clearing trends.

# **Memory Capacity**

The trend interval affects the maximum trend record length. The trend interval is fixed at 4 seconds, and the total record length is 6 days. If the total trend record length is exceeded for all patients combined, each new trend entry will replace the oldest overall trend entry.

# **Clearing Trend Data**

To clear all of the trend memory and reset the patient record number to P, turn the monitor off. Then push and hold the on/off % key until "P," stops flashing in the Pulse Rate display and P; is displayed. This takes about 15 seconds.

If the key is released at any time before **[Lr** stops flashing, the memory is retained, and the configuration settings are displayed. (See *Checking the Monitor's Configuration* section in Chapter 4 for details.)

# **Trend Data Output**

Trend data may be output to a printer or PC. See *Chapter 6*: Optional Docking Station and Printer for information on printing trend data. See *Chapter 7*: Connecting to a PC, for information about PC output.

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# **Chapter 6: Optional Docking Station and Printer**

# **Description**

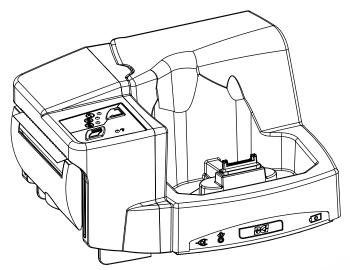


Figure 6-1: Docking Station with Printer Attached

The WW1025 Docking Station serves many purposes depending on individual needs and selection of optional equipment. The Docking Station is powered by the WW1095 AC Power Supply, which can power the oximeter and operate the printer while charging the internal and spare battery packs.

### The Docking Station:

- Provides a convenient and secure "home base" for the oximeter.
- Recharges WW1090 Lithium-lon (Li+) rechargeable battery pack installed in the oximeter.
- Recharges an additional WW1090 Lithium-Ion (Li+) rechargeable battery pack stored in the Docking Station.
- May be equipped with a WW1026 thermal printer.
- Allows connection to a PC for trend memory dump.
- Transfers USB power to the oximeter if no AC is connected (only when the USB interface cable, WW1089, is connected to an active source of USB power).

# **Docking Station**

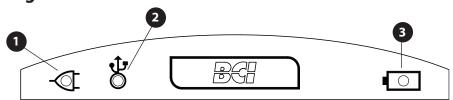


Figure 6-2: Indicators on Docking Station Front Panel

- AC Power Indicator
  - This indicator will light when AC power is connected to the Docking Station.
- 2 USB Power Indicator
  This indicator will light when a USB cable is connected to the Docking Station, but AC power is not.
- This indicator will flash green when the WW1090 Lithium-Ion (Li+) rechargeable battery pack is charging. After the battery is fully charged, the indicator lights solid green. Battery or charging errors are indicated by a yellow LED. See *Chapter 9: Troubleshooting* for details.

### **Powering the Docking Station**

- WARNING! Do not plug the Docking Station AC power supply into an outlet controlled by a wall switch.
- WARNING! Do not allow any moisture to contact the AC power supply connectors, or a safety hazard may result. Ensure that hands are thoroughly dry before handling the AC power supply.
- WARNING! Do not place the Docking Station in the patient's bed or crib. Do not place the Docking Station on the floor.
- WARNING! Failure to place the Docking Station away from the patient may allow the patient to turn off, reset, or damage the monitor, possibly resulting in the patient not being monitored. Make sure the patient cannot reach the monitor from their bed or crib.

The WW1095 AC Power Supply provides power to the Docking Station and connected accessories. Connect the AC Power Supply to the dock using the data port or Power Input Connector. The Docking Station's AC power indicator ( ) will light when AC power is connected. The Docking Station has built-in intelligence that prioritizes available power to the oximeter, printer and chargers. If USB power is used for the Docking Station, some accessories may not operate.

When the WW1089 USB interface cable is connected to the Docking Station, data can be transferred from the oximeter's data port through the Docking Station to a compatible device. If the USB cable is used without AC power, the USB ( ) indicator is lit, and USB power is available to the oximeter.

NOTE! The WW1090 Lithium-Ion (Li+) Rechargeable Battery Pack can be fast charged by installing it in the oximeter and supplying power, using the AC Power Supply either directly or through the Docking Station. The WW1090 Li+ Rechargeable Battery Pack can also be fast charged by installing it directly in the Docking Station and supplying power using the AC Power Supply.

NOTE! To slow charge the WW1090 Lithium-Ion (Li+) Rechargeable Battery Pack, install the Battery Pack in the oximeter and connect to USB power. Slow charging may take 20 hours or more. USB power cannot charge the spare Li+ Rechargeable Battery Pack in the Docking Station.

NOTE: USB power may fail if AC power is interrupted to its PC or powered USB hub. Always use charged batteries in the oximeter.

### WW1090 Lithium-Ion (Li+) Rechargeable Battery Pack

The Docking Station (when powered by the WW1095 AC Power Supply) will charge two WW1090 Lithium-lon (Li+) rechargeable battery packs simultaneously. It will recharge the currently installed oximeter battery pack as well a spare pack mounted in the Docking Station battery charger.

The WW1090 Lithium-Ion (Li+) rechargeable battery pack is placed in the dock as shown in figure 6-3. When the battery is charging, the indicator ( ) flashes green. After the battery is fully charged, the indicator ( ) lights solid green. Battery or charging errors are indicated by a yellow LED. See *Chapter 9: Troubleshooting* for details.

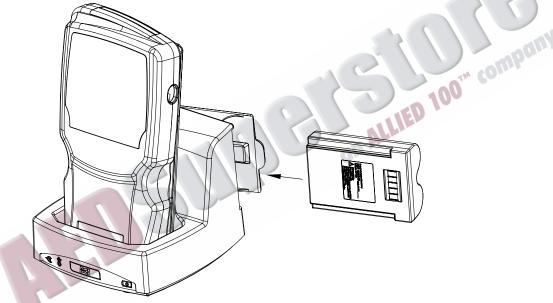


Figure 6-3: Connecting the Rechargeable Battery Pack

NOTE: The battery in the Docking Station battery charger cannot power the oximeter without being installed in the oximeter. In the event of loss of power to the Docking Station, the spare battery will not automatically provide power.

### **Installing the Oximeter to the Dock**

The WW1020/WW1000 is placed bottom first into the Docking Station facing out as shown in figure 6-3. Confirm that good connection is made by observing that the oximeter's external power indicator ( ( ) is lit.

### **Downloading Data to PC**

Data may be sent to a computer through the Docking Station using the WW1089 USB Interface Cable. See *Chapter 7: Connecting to a PC* for details.

### **Printer**

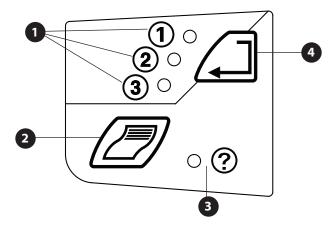


Figure 6-4: Printer Keys and Indicators

1 Print Mode Indicators

These indicators light according to what print mode is selected. See Choosing the Print Mode section later in this Chapter.

The Print Mode Indicator will blink green when printing is pending or in progress.

- 2 Start/Stop Print Key
- Trint Error Indicator
  This indicator will light if there is an error in printing.

  Select Print Mode Key

  Press this key to char Print Error Indicator
- 4 Select Print Mode Key

### **Attaching the Printer**

The optional WW1026 thermal printer attaches to the Docking Station with a single screw as shown in Figure 6-5C. Follow the steps below.

WARNING! The Docking Station must have a Printer or Printer Port Cover installed. Failure to do so may cause a risk of electrical shock to the patient or operator or risk damage to the equipment.

To attach the printer to the Docking Station:

1. Remove the oximeter and battery and disconnect any cable from the Docking Station.

NOTE: Failure to remove the oximeter and battery from the Docking Station prior to installing the printer will result in an error which may cause a faulty printout.

2. Remove the Docking Station printer port cover.



Remove port cover using a screwdriver

Figure 6-5A: Remove the Docking Station Printer Port Cover

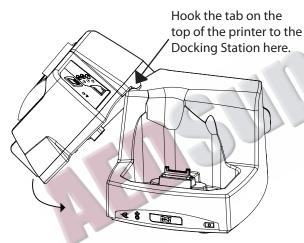
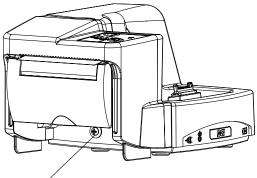


Figure 6-5B: Align and Connect the Dock and Printer

ALLIED 100" company 3. Hook the tab on the top of the printer to the groove at the top of the Docking Station. Then swing the printer down to align and attach the printer to the dock's electrical connectors.

- 4. Install the screw as shown in figure 6-5C.
- 5. Reconnect any cables and replace the oximeter and battery.
- 6. The printer is now ready to load paper.



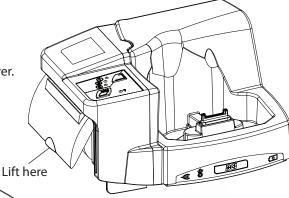
Install screw here

Figure 6-5C: Mate and Align the Dock and Printer

### **Loading Paper**

The printer uses 58mm wide thermal paper. See Chapter 10: Optional Supplies & Accessories for part number and ordering information. To load the paper, follow the steps illustrated below.

1. Release printer door by lifting clear cover.



2. Swing open paper holder by continuing to pull on clear door.

Figure 6-6A: Release Printer Door

3. Remove existing spool if present.

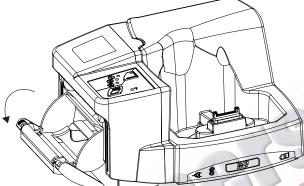


Figure 6-6B: Swing Open Paper Holder

Place paper spool in holder so that the paper exits over the top of the roll and drapes over the rubber roller as shown in figure 6-6C.

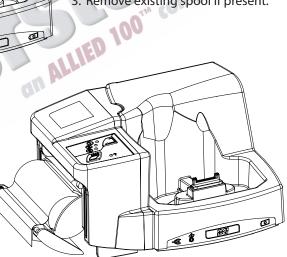


Figure 6-6C: Place Paper Spool in Holder

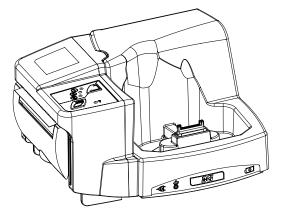


Figure 6-6D: Close Paper Holder Door and Clear Cover

- 5. Close the paper holder door and the clear cover.
- 6. Tear off any excess paper by pulling the paper up toward the front of the printer.
- 7. The printer is now ready to use.

# **Choosing the Print Mode**

Data can be printed in real time, numeric trend or graphic trend modes. In either trend mode, 6 days of previously stored data (depending on trend interval) collected from 1 to 99 patients can be printed. See *Chapter 5: Patient Record Number and Trend Data*. The printer select key sets the printer mode in the oximeter. When a new oximeter is installed in the Docking Station, it may have a different print format. Always check the printer format prior to pushing the start key.

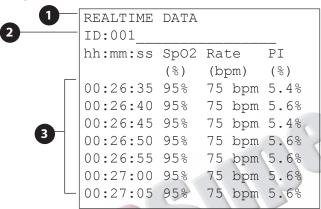
Change modes by pushing the select key ( ) until the desired mode is lit.

To start printing, push the print ( $\overline{\mathbb{P}}$ ) key. The Print Mode Indicator on the printer will blink green when printing is pending or in progress.

NOTE: The oximeter must be installed in the Docking Station to print.

### NOTE: Thermal paper must be installed.

Mode 1 - Real Time Mode prints data every 5 seconds. See figure 6-7.

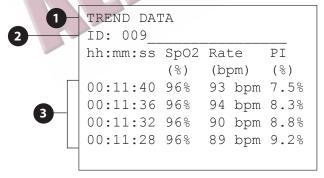


1 Title

- 2 Patient Record Number
- Real time %SpO<sub>2</sub>, pulse rate and PI values printed every 5 seconds

Figure 6-7: Sample Real Time Data Log

Mode 2 - Numeric Trend Data prints in a tabular form. See figure 6-8.



1 Title

- 2 Patient Record Number
- Trended %SpO<sub>2</sub>, pulse rate and PI values printed every 4 seconds

Figure 6-8: Sample Numeric Trend Data

Mode (3) - Graphic Trend Mode prints in a chart format See figure 6-9.

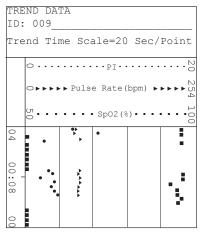


Figure 6-9: Sample Graphic Trend

NOTE! While printing trends, the printer will pause for approximately 20 seconds after 10 seconds of printing. This allows the thermal print head to cool. A small gap may appear on each printout when printing resumes.

NOTE! Invalid SpO<sub>2</sub> data and SpO<sub>2</sub> values between 0 and 50 will be printed as 50.

# **Trend Data Condition Flags**

Each time a trend interval occurs and data is stored, certain conditions, active at that time, are stored with the data. These are indicated by symbols on the print out.

CONDITION	SYMBOL	DESCRIPTION
Artifact (WW1020 only)	Mv	Artifact indicator informs user of excess motion, noise or other signal information that the algorithm interprets as potentially non-physiological.  This flag is an indicator that pulse rate data has changed and now may be invalid.
Small Pulse (WW1020 only)	ll.	Indicates the signal strength is ≤ 3.
Check Sensor	<b>4</b>	Indicates a problem with sensor placement or that no sensor is plugged into the sensor connector. No valid parameter data is available.
Searching too Long	84	Only displayed if the oximeter has not detected a valid pulse at any time after power up. Indicates that the oximeter has searched for more than 20 seconds but no pulse was detected.
Lost Pulse	<b>Ø</b>	Indicates the oximeter has searched for more than 20 seconds, a finger is detected in the sensor, but a previously detected pulse is no longer present.

# **Chapter 7: PC Communication Setup**

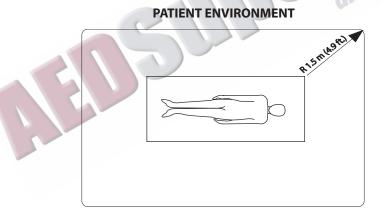
# **Description**

Real Time and Trend Data may be sent to a PC from the oximeter in the following ways:

- The Data/Power Connector of the oximeter or of the Docking Station may be connected to a PC using the USB Interface Cable (REF) WW1089). Trend data or Real Time patient data will be downloaded using a proprietary data protocol.
- The oximeter sensor can be replaced with the WW3350 or 3339 cable to transfer commaseparated value (.CSV) ASCII Trend Data via RS232.

WARNING! When connecting this monitor to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. Accessory equipment connected to the monitor's data interface must be certified according to the respective IEC standards, i.e., IEC 60950 for data processing equipment or IEC 60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC 60601-1-1 systems requirements. Anyone connecting additional equipment to the signal input port or the signal output port configures a medical system, and, therefore, is responsible that the system complies with the requirements of the system standard IEC 60601-1-1.

WARNING! IEC 60950 approved equipment must be placed outside the "patient environment". The patient environment is defined as an area 1.5 m (4.92 feet) from the patient.

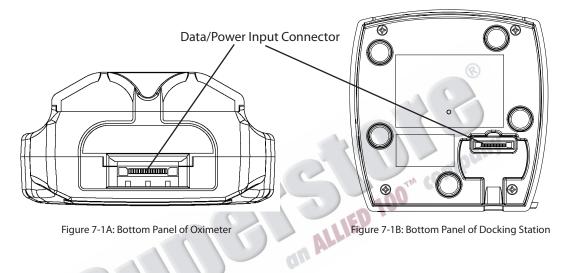


# **Power Input and Data Connector Port**

Data can be transferred to a computer running software that is compatible with the specialized data format BCICP1030 by using the USB Interface Cable.

The following items will be needed:

- Oximeter with or without the Docking Station
- User Compatible PC Application Software
- USB Interface Cable (REF WW1089)
- AC Power Supply (optional)



### **How to Set Up Equipment**

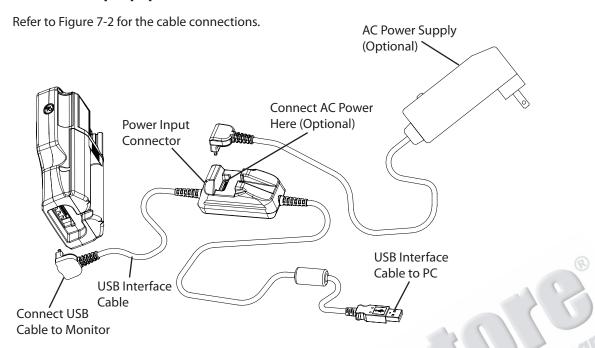


Figure 7-2: Connecting to a PC using USB Interface Cable

- 1. Connect the USB interface cable to the I / O or Power Input Connector on the oximeter or Docking Station.
- 2. If using the WW1095 AC Power Supply, connect it to the PC cable power input connector.
- 3. Connect the interface cable to the PC's USB port.
- 4. The oximeter is now ready to download data.

The BCICP1030 data output format is available upon request.

NOTE! Review the PC communication program's instructions to determine how to save the data to the PC.

### Sensor / RS232 Port

Trend data may be downloaded in a comma-separated value (.CSV) format to a computer's serial (RS232) port.

The following items will be needed:

- Oximeter
- HyperTerminal or other PC communication software
- WW3350 Printer Adaptor cable
- 3339 PC Adaptor cable

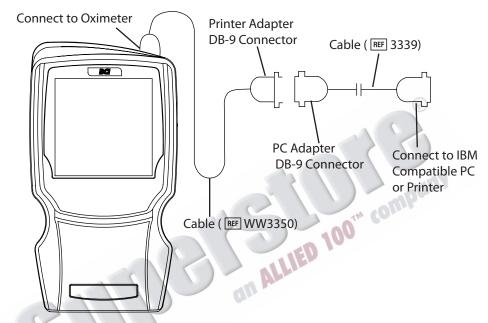


Figure 7-3: Connecting to the RS232 Port

## **How to Set Up Equipment**

Refer to Figure 7-3 for the cable connections.

- 1. Setup the PC communication program to accept the following RS232 data format:
  - Data Type: ASCII
  - Data Format: 9600 baud, 1 start bit, 8 data bits 1 stop bit, no parity
  - Select any available RS232 Com Port (typically com1 or com2)
- 2. Turn off the oximeter.
- 3. Remove the oximetry sensor from the sensor connector.
- 4. Connect the printer adaptor cable (WW3350) to the sensor connector. Make sure the "BCI" end is connected to the oximeter.
- 5. Connect the PC adaptor cable's DB-9 connector to the mating connector of the printer cable labeled "Printer".
- 6. Connect the other end of the PC adaptor cable to the PC's RS232 Com Port selected in step 1.
- 7. Turn on the oximeter to start sending all of the stored trend data to the PC.

NOTE! Review the PC communication program's instructions to determine how to save the data to the PC.

### **Output Format**

Trend data is transmitted in the format shown in Figure 7-4.

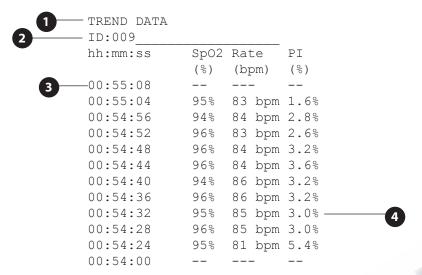


Figure 7-4: Typical ASCII Trend Data Output

- 1 Title
- **2** Patient Record Number
- 3 Newest data sample is printed first. Dashes mean no measurements were available at that sample time.
- 4 Trended %SpO<sub>2</sub>, pulse rate and PI values print every 4 seconds

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# **Chapter 8: Maintenance**

Smiths Medical PM, Inc. products have been designed to operate continuously. However, in order to ensure a continued high level of performance and safety of operation, routine maintenance must be performed daily.

The Oximeter Service Manual (REF) WW1923) also contains the circuit diagrams, parts lists, and descriptions required for carrying out repairs. The Service Manual is shipped with the monitor.

## **Routine Maintenance**

MAINTENANCE ITEM	RECOMMENDED ACTION	MAINTENANCE INTERVAL
WW1090 Li-lon rechargeable battery pack	Charge the battery by connecting AC power to the monitor.	When Low Battery Signal is observed.
		After continuous use under battery power.
	Replace the rechargeable battery pack.	After approximately 300 charge cycles.
Monitor Surfaces and Docking Station /Printer	Clean and/or disinfect	As required.
Cables	Clean and/or disinfect	When attaching a new patient.
	Inspect for signs of damage or deterioration; replace as required	Daily. ALLIED
Reusable SpO <sub>2</sub> sensor	Clean and/or disinfect	When attaching a new patient.

# **Cleaning and Disinfecting**

WARNING! Do not autoclave, ethylene oxide sterilize, or immerse the monitor in liquid.

Clean the surfaces of the monitor with a soft cloth moistened in water or a mild soap solution. If disinfecting is necessary, wipe the surfaces of the monitor with a 70% isopropyl alcohol solution. If there is contamination with blood borne pathogens or other potentially infectious materials, then the use of an approved disinfectant of appropriate spectrum for the suspected organisms is appropriate. Then wipe the surfaces with a soft, water-moistened cloth.

- WARNING! Do not allow water, isopropyl alcohol or any other liquid to enter any of the openings on the monitor. Unplug the AC power cord from the monitor before cleaning or disinfecting.
- CAUTION! Where the equipment has accidentally gotten wet, it should be wiped dry externally and allowed to dry thoroughly before use.
- CAUTION! Before cleaning or disinfecting the printer, unplug the AC adapter, remove the batteries and remove the paper.
- CAUTION! Do not allow printer paper to become wet. If the printer paper gets wet, remove the paper immediately. Do not use the printer until the paper is replaced.
- CAUTION! Disinfectant chemicals may affect the outer case over prolonged use, however disinfection must be performed.
- NOTE! Use only a soft cotton cloth to clean the monitor's screen. Do not clean the screen with tissues, paper towels, or any other paper-based wipe. Paper-based wipes can scratch the screen.

# Storage

Whenever possible, the monitor should be stored inside at room temperature in a dry environment. If it is necessary to store the monitor for an extended period of time, the unit should be packed in its original shipping container. Storing the monitor for a long period of time may degrade the battery capacity. Batteries should be removed from the monitor before storing.

See Chapter 11 for storage specifications.

NOTE! The monitor may not meet performance specifications when stored or used outside the temperature and humidity ranges listed in *Chapter 11: Specifications*.

# **Chapter 9: Troubleshooting**

WARNING! If the accuracy of any measurement is in question, check the patient's vital signs by an alternative method, and then check the monitor for proper functioning.

## **Power**

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
The oximeter doesn't turn on.	Batteries weak and/ or no AC power.	Replace or recharge the batteries. Connect to source of AC power.
	Batteries not installed or batteries incorrectly installed.	Ensure the batteries are installed correctly.
		Connect to source of AC power.
The oximeter turns on, but display reads: LU bRL	AC power is connected, but no or weak batteries are installed.	This is proper operation. Replace or recharge the batteries.
The oximeter turns off unexpectedly.	Batteries are weak or dead and no AC power source is connected.	Replace or recharge the batteries. Connect to source of AC power.
The External Power indicator ⇒ is not lit (AC Power).	An External AC Power Supply cord is not connected to the monitor or accessory cable. The accessory cable is not connected to the monitor.	Check all power supplies and cables for proper connections.
	The AC power cord is connected to a wall outlet that is controlled by a wall switch.	Only connect the AC power cord to an outlet that is not controlled by a wall switch.
	A non user-serviceable fuse may have opened.	Contact your authorized service representative.
The External Power indicator	The USB cable is not connected to a source of power or the USB power source is not operating.	Check all cable connections and confirm PC, USB hub or other source of USB power is working correctly.
The USB Power indicator 🕩 is not	AC Power is connected.	This is proper operation.
lit. (Docking Station)	The USB cable is not connected to a source of power or the USB power source is not operating.	Check all cable connections and confirm PC, USB hub or other source of USB power is working correctly.
The monitor operates on AC	The battery is missing.	Replace the battery.
power, but not on battery power.	The battery is drained.	Charge or replace the battery. Replace the battery
	The battery is defective.	Contact your authorized service representative if using LI-lon rechargeable battery pack.

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
The monitor displays  27  Err when powered up.	The battery is defective.	Disconnect the AC power cord and then reconnect it. If the error message persists, the battery is defective. Contact your authorized service representative.
Battery run time is excessively short on a fully charged battery.	The LI-lon rechargeable battery pack must be replaced.	Contact your authorized service representative.

# Sensor

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
No pulse shown on the bargraph or Pl graph.	Patient cable or sensor is disconnected from the oximeter.	Check sensor connections to the patient cable and to the oximeter.
угарп.	Sensor is incorrectly positioned on the patient.	Reposition the sensor.
	Poor patient perfusion.	Reposition the sensor.
	Defective sensor or patient cable.	Try a new sensor or contact your authorized service representative for help.
The pulse rate is erratic, intermittent, or incorrect.	The SpO <sub>2</sub> sensor is improperly positioned on the patient.	Reposition the sensor on the patient.
	The patient is experiencing poor perfusion.	Confirm signal level with PI and signal bar graphs.Reposition the sensor on the patient.
	The patient is moving too much.	Make sure that the patient remains still. Place the extremity on a pillow that acts as a buffer to motion.
	There is too much ambient light around the SpO <sub>2</sub> sensor.	Shield the SpO <sub>2</sub> sensor with a towel.
	Defective sensor or patient cable.	Try a new sensor or contact your authorized service representative for help.
SpO <sub>2</sub> value is erratic, intermittent, or	Poor patient perfusion.	Confirm signal level with PI and signal bar graphs.
incorrect.	Patient motion.	Reposition the sensor on the patient. Patient must remain still to obtain an accurate measurement.
	Defective sensor or patient cable.	Try a new sensor or contact your authorized service representative for help.

# Other

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
No printout on optional printer.	AC power is not connected to the Docking Station.	Connect AC Power to the Docking Station.
	No trends in memory.	Take trend data.
	No paper or paper incorrectly loaded.	See Chapter 6: Optional Docking Station and Printer for details of loading paper.
"?" malfunction indicator on the printer is lit.	Printer interface malfunction.	Contact your authorized service representative for help.
printer is it.	Printer door open.	Close the printer door.
	Printer out of paper.	Install a roll of printer paper.
Real time or trend data is not transmitted.	An accessory cable is defective.	Contact your authorized service representative.
	Oximeter is not properly seated in Docking Station.	Remove the oximeter from the Docking Station and replace it assuring proper alignment.
	The communications setup is not correct.	Check the user-connected auxiliary equipment and software.
Display shows	Remote alarm cable attached to the oximeter.	This is proper operation. The WW1020 and WW1000 are not intended for use with the remote alarm cable.
Display shows  5  Err	No sensor attached to the oximeter.	Attach a sensor to the oximeter.
	Defective sensor or patient cable.	Try a new sensor. If the problem persists, contact your authorized service representative.
Display shows 24 Err	EEPROM checksum Error	Contact your authorized service representative.
Display shows 25 Err	Trend Checksum Error	Contact your authorized service representative.
Display shows <b>Err</b>	Internal oximetry failure.	Contact your authorized service representative.

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# **Chapter 10: Optional Supplies and Accessories**

CAT. NO.	DESCRIPTION	QTY.
WW1000	Pulse Oximeter	each
WW1018R	Protective glove - red	each
WW1018Y	Protective glove - yellow	each
WW1018G	Protective glove - green	each
WW1018B	Protective glove - blue	each
WW1020	Pulse Oximeter (with Serial Autocorrelation)	each
WW1025	Docking Station	each
WW1026	Printer (Must be used with Docking Station WW1025)	each
WW1027	Thermal Printer Paper	5/pk
WW1080	Replacement Sensor Cradles (3)	set
WW1081	Rubber Feet for Mounting Bracket - Replacement	pair
WW1089	USB interface cable	each
WW1090	Rechargeable battery pack, LI-Ion	each
WW1095	Universal AC mains adapter - 30W	each
WW1098	Universal Mounting Bracket	each
WW1101	Mounting Bracket Strap - Replacement	each
1300	Sensor, Oximetry, Disposable, Adult Finger	10/box
1301	Sensor, Oximetry, Disposable, Pediatric. Finger, 15-45 kg	10/box
1302	Sensor, Oximetry, Disposable, Neonate/Small Infant, < 3 kg*	10/box
1303	Sensor, Oximetry, Disposable, Infant, 3-15 kg	10/box
1606	Simulator, Oximeter	each
WW1922	Manual, Operation	each
WW1923	Manual, Service	each
3025	Sensor, Oximetry, Wrap, Infant, 3-15 kg	each
3026	Sensor, Oximetry, Wrap, Neonate/Small Infant, < 3 kg*	each
3043	Sensor, Oximetry, Universal 'Y'	each
3044	Sensor, Oximetry, Finger	each
30445	Spot Check Sensor, Reusable, Adult	each
3049	Microfoam Strips, Adhesive for use with 3025, 3026 and 3043	40/pkg
WW3078	Sensor, Oximetry, Ear	each
3134	Tape, Attachment, Neonatal/Small Infant	50/pkg
3135	Tape, Attachment, Infant	50/pkg
3136	Tape, Attachment, Neonatal/Small Infant	100/pkg
3137	Tape, Attachment, Infant	100/pkg
3138	Posey Wrap, Attachment, Universal 'Y' for use with 3025, 3026 and 3043	10/pkg
3178	Sensor, Pediatric Finger, 5-45 kg	each
31785	Spot Check Sensor, Reusable, Pediatric	each
3311	Cable, Oximetry, 1.5 m (5 feet)	each

<sup>\*</sup> The BCI® 1302 and 3026 oximetry sensors should not be used on neonatal patients with the WW1000 monitor. Testing has not been conducted for the WW1000 for patients less than 30 days old. These sensors may, however be used on older patients.

Chapter 10: Optional Supplies and Accessories

CAT. NO.	DESCRIPTION	QTY.
3339	PC adapter cable	each
WW3350	Printer adapter cable	each
3444	Sensor, Oximetry, Finger, Comfort Clip®	each

# **Ordering Information**

Outside the USA, for ordering information, contact your local distributor. In the USA, for ordering information, contact the customer service department at the address or phone number below:

Smiths Medical PM, Inc. Phone: (262) 542-3100

N7W22025 Johnson Drive Toll-Free: (800) 558-2345 (USA only)

Waukesha, WI 53186 USA Fax: (262) 542-0718

web site: www.smiths-medical.com
E-mail address: info.pm@smiths-medical.com

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# **Chapter 11: Specifications**

# **Displays**

2-digit LED display, 19 mm high. SpO<sub>2</sub>: Pulse Rate: 3-digit LED display, 12.7 mm high.

PI: 9-segment LED bar graph.

Pulse Signal Strength: Logarithmically scaled 9-segment LED bar graph.

Display update rate

SpO<sub>3</sub> and Pulse rate: 2Hz All other data: 10Hz Display Refresh: 50 Hz

### **Indicators**

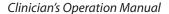
Visual

External Power indicator: ( — green) with power plug icon.

ALLIED 100<sup>th</sup> company Battery charge indicator: ( green/yellow) with 4 segment gauge; green if 2-4 segments

# **Keys/User Controls**

On/Off Key (%)



# SpO<sub>2</sub> for the WW1020 Oximeter

SpO<sub>2</sub> Range: 0-100% Functional Saturation (Display Maximum: 99%)

SpO<sub>2</sub> Resolution: 1 count (%SpO<sub>2</sub>)

SpO<sub>2</sub> Averaging: 8 beats

Calibration: Factory calibrated over range 70% to 100% SpO<sub>2</sub> using human blood

samples to functional saturation. Test methods are available upon request.

No in-service calibration is required.

Sensors: Red: 660 nm, 2 mW (typical)

Infrared: 905 nm, 2-2.4 mW (typical)

SpO<sub>2</sub> Accuracy: 70 to 100% SpO<sub>2</sub>, less than 70% SpO<sub>2</sub> is undefined.

Sensor	SpO₂ Accuracy in Normal Conditions <sup>1, 2</sup>	SpO₂ Accuracy in Low Perfusion Conditions <sup>1, 3</sup>	SpO₂ Accuracy in Motion Conditions <sup>15</sup>
BCI® 1300	±2 Arms	±2 <sup>9</sup> A <sub>RMS</sub>	±3 Arms
BCI® 1301	±2 <sup>4</sup> A <sub>RMS</sub>	±2 <sup>9</sup> A <sub>RMS</sub>	±3 <sup>13</sup> A <sub>RMS</sub>
BCI® 1302	±3 <sup>14</sup> A <sub>RMS</sub>	±3 <sup>14</sup> A <sub>RMS</sub>	unspecified
BCI® 1303	±2 <sup>5</sup> Arms	±2 <sup>9</sup> Arms	unspecified
BCI® 3025	±2.5 <sup>6</sup> A <sub>RMS</sub>	±2.5 <sup>10</sup> A <sub>RMS</sub>	unspecified
BCI® 3026	±3.5 <sup>14</sup> A <sub>RMS</sub>	±3.5 <sup>14</sup> A <sub>RMS</sub>	unspecified
BCI® 3043	±3 Arms	±3 Arms	unspecified
BCI® 3044	±2 A <sub>RMS</sub>	±2 A <sub>RMS</sub>	unspecified
BCI® 3044S	±2 <sup>7</sup> A <sub>RMS</sub>	±2 11 A <sub>RMS</sub>	unspecified
BCI® 3078	±3.6 Arms	±3.6 A <sub>RMS</sub>	unspecified
BCI® 3178	±2 A <sub>RMS</sub>	±2 A <sub>RMS</sub>	unspecified
BCI® 3178S	±2 8 A <sub>RMS</sub>	±2 <sup>12</sup> A <sub>RMS</sub>	unspecified
BCI® 3444	±2 A <sub>RMS</sub>	±2 Arms	unspecified
Nellcorr® DS100A	±2.5 A <sub>RMS</sub>	±2.5 A <sub>RMS</sub>	unspecified

Because pulse oximeter measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within the  $\pm$  A<sub>RMS</sub> of the value measured by the CO-oximeter.

<sup>&</sup>lt;sup>2</sup>The WW1020 has been validated on 10 adult volunteers that did not have health problems and were non-smokers. The study was conducted at oxygen concentrations evenly distributed over an SpO<sub>2</sub> range of 70-100%.

<sup>&</sup>lt;sup>3</sup> Pulse Amplitude 1% to 0.1%. Tested using industry standard simulator.

<sup>&</sup>lt;sup>4</sup>Clinical accuracy based on BCI® 1300; <sup>5</sup>Clinical accuracy based on BCI® 1302.

<sup>&</sup>lt;sup>6</sup>Clinical accuracy based on BCI<sup>®</sup> 3026; <sup>7</sup>Clinical accuracy based on BCI<sup>®</sup> 3044.

<sup>&</sup>lt;sup>8</sup> Clinical accuracy based on BCI® 3178; <sup>9</sup> Clinical accuracy based on BCI® 1302.

<sup>&</sup>lt;sup>10</sup> Clinical accuracy based on BCI® 3026; <sup>11</sup> Clinical accuracy based on BCI® 3044.

<sup>&</sup>lt;sup>12</sup> Clinical accuracy based on BCI® 3178; <sup>13</sup> Clinical accuracy based on BCI® 1300.

<sup>&</sup>lt;sup>14</sup>For neonatal patients, 1%-SpO<sub>2</sub> was added to account for theoretical differences in pulse oximetry function between adult and neonatal hemoglobin. This investigation was performed on adults only.

<sup>&</sup>lt;sup>15</sup> Motion patterns used consisted of tapping and rubbing. Subjects varied the motion frequencies to a maximum of 300 cycles per minute. A maximum amplitude of approximately 2.5 cm was used in this study.

## Pulse Rate for the WW1020 Oximeter

Pulse Rate Range: 20-300 bpm

Pulse Rate Resolution: 1 BPM
Pulse Rate Averaging: 8 seconds

Pulse Rate Accuracy:

Sensor	Pulse Rate Accuracy in Normal Conditions <sup>1</sup> 20-300bpm	Pulse Rate Accuracy in Low Perfusion Conditions <sup>2</sup> 25-250bpm	Pulse Rate Accuracy in Motion Conditions 20-300bpm
BCI® 1300	±2 A <sub>RMS</sub>	±3 <sup>3</sup> A <sub>RMS</sub>	unspecified
BCI® 1301	±2 A <sub>RMS</sub>	±3 <sup>3</sup> A <sub>RMS</sub>	unspecified
BCI® 1302	±2 A <sub>RMS</sub>	±3 A <sub>RMS</sub>	unspecified
BCI® 1303	±2 A <sub>RMS</sub>	±3 <sup>3</sup> A <sub>RMS</sub>	unspecified
BCI® 3025	±2 A <sub>RMS</sub>	±3 <sup>4</sup> A <sub>RMS</sub>	unspecified
BCI® 3026	±2 A <sub>RMS</sub>	±3 A <sub>RMS</sub>	unspecified
BCI® 3043	±2 A <sub>RMS</sub>	±3 A <sub>RMS</sub>	unspecified
BCI® 3044	±2 A <sub>RMS</sub>	±3 A <sub>RMS</sub>	unspecified
BCI® 3044S	±2 A <sub>RMS</sub>	±3 <sup>5</sup> A <sub>RMS</sub>	unspecified
BCI® 3078	±2 A <sub>RMS</sub>	±3 <sup>6</sup> A <sub>RMS</sub>	unspecified
BCI® 3178	±2 A <sub>RMS</sub>	±3 A <sub>RMS</sub>	unspecified 1 <sup>th</sup>
BCI® 3178S	±2 A <sub>RMS</sub>	±3 <sup>7</sup> A <sub>RMS</sub>	unspecified
BCI® 3444	±2 A <sub>RMS</sub>	±3 A <sub>RMS</sub>	unspecified
Nellcorr® DS100A	±2 A <sub>RMS</sub>	±3 A <sub>RMS</sub>	unspecified

<sup>&</sup>lt;sup>1</sup> Pulse Amplitude 6%. Tested using industry standard simulator.

<sup>&</sup>lt;sup>2</sup> Pulse Amplitude 1% to 0.1%. Tested using industry standard simulator.

<sup>&</sup>lt;sup>3</sup> Low Perfusion simulator accuracy specification based on BCI® 1302.

<sup>&</sup>lt;sup>4</sup>Low Perfusion simulator accuracy specification based on BCI® 3026.

<sup>&</sup>lt;sup>5</sup> Low Perfusion simulator accuracy specification based on BCI® 3044.

<sup>&</sup>lt;sup>6</sup> Pulse Amplitude 1% to 0.3%. Tested using industry standard simulator.

<sup>&</sup>lt;sup>7</sup>Low Perfusion simulator accuracy and specification based on BCI® 3178.

# SpO<sub>2</sub> for the WW1000 Oximeter

SpO<sub>2</sub> Range: 0-99% Functional Saturation

 $SpO_2$  Resolution: 1 count (% $SpO_2$ )

SpO<sub>2</sub> Averaging: 8 beats

Calibration: Factory calibrated over range 70% to 99% SpO<sub>2</sub> using human blood samples

to functional saturation. Test methods are available upon request. No in-

service calibration is required.

Sensors: Red: 660 nm, 2 mW (typical)

Infrared: 905 nm, 2-2.4 mW (typical)

 $SpO_2$  Accuracy: 70 to 99%  $SpO_2$ , less than 70%  $SpO_2$  is undefined.

BCI® Sensor	SpO <sub>2</sub> Accuracy in Normal Conditions <sup>1, 2</sup>	SpO <sub>2</sub> Accuracy in Low Perfusion Conditions <sup>1, 3</sup>
1300	±2 A <sub>RMS</sub>	±2 <sup>8</sup> A <sub>RMS</sub>
1301	±2 <sup>4</sup> A <sub>RMS</sub>	±2 <sup>8</sup> A <sub>RMS</sub>
1302	±2 <sup>4</sup> A <sub>RMS</sub>	±2 A <sub>RMS</sub>
1303	±2 <sup>4</sup> A <sub>RMS</sub>	±2 <sup>8</sup> A <sub>RMS</sub>
3025	±2.5 <sup>5</sup> A <sub>RMS</sub>	±2.5 <sup>9</sup> A <sub>RMS</sub>
3026	±2.5 A <sub>RMS</sub>	±2.5 A <sub>RMS</sub>
3043	±3 A <sub>RMS</sub>	±3 A <sub>RMS</sub>
3044	±2 A <sub>RMS</sub>	±2 A <sub>RMS</sub>
30445	±2 <sup>6</sup> A <sub>RMS</sub>	±2 <sup>10</sup> A <sub>RMS</sub>
3078	±3 A <sub>RMS</sub>	±3 <sup>11</sup> A <sub>RMS</sub>
3178	±2 A <sub>RMS</sub>	±2 A <sub>RMS</sub>
31785	±2 <sup>7</sup> A <sub>RMS</sub>	±2 <sup>12</sup> A <sub>RMS</sub>
3444	±2 A <sub>RMS</sub>	±2 A <sub>RMS</sub>

<sup>&</sup>lt;sup>1</sup> Because pulse oximeter measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within the  $\pm$  A<sub>RMS</sub> of the value measured by the CO-oximeter.

<sup>&</sup>lt;sup>2</sup>The WW1000 has been validated on 10 adult volunteers that did not have health problems and were non-smokers. The study was conducted at oxygen concentrations evenly distributed over an SpO<sub>2</sub> range of 70-100%.

<sup>&</sup>lt;sup>3</sup> Pulse Amplitude 1% to 0.1%. Tested using industry standard simulator.

<sup>&</sup>lt;sup>4</sup>Clinical accuracy based on BCI® 1300.

<sup>&</sup>lt;sup>5</sup> Clinical accuracy based on BCI® 3026.

<sup>&</sup>lt;sup>6</sup>Clinical accuracy based on BCI® 3044.

<sup>&</sup>lt;sup>7</sup>Clinical accuracy based on BCI® 3178.

<sup>&</sup>lt;sup>8</sup> Low Perfusion simulator accuracy and specification based on BCI® 1302.

<sup>&</sup>lt;sup>9</sup>Low Perfusion simulator accuracy and specification based on BCI® 3026.

<sup>&</sup>lt;sup>10</sup> Low Perfusion simulator accuracy and specification based on BCI® 3044.

<sup>&</sup>lt;sup>11</sup> Pulse Amplitude 1% to 0.3%. Tested using industry standard simulator.

<sup>&</sup>lt;sup>12</sup> Low Perfusion simulator accuracy and specification based on BCI® 3178.

## Pulse Rate for the WW1000 Oximeter

Pulse Rate Range: 30-254 bpm

Pulse Rate Resolution: 1 bpm
Pulse Rate Averaging: 8 seconds

Pulse Rate Accuracy:

Pulse Rate Accuracy BCI® Sensor in Normal Conditions <sup>1</sup> 30-254bpm		Pulse Rate Accuracy in Low Perfusion Conditions <sup>2</sup> 30-250bpm
1300	±2 A <sub>RMS</sub>	±3 <sup>3</sup> A <sub>RMS</sub>
1301	±2 A <sub>RMS</sub>	±3 <sup>3</sup> A <sub>RMS</sub>
1302	±2 A <sub>RMS</sub>	±3 A <sub>RMS</sub>
1303	±2 A <sub>RMS</sub>	±3 <sup>3</sup> A <sub>RMS</sub>
3025	±2 A <sub>RMS</sub>	±3 <sup>4</sup> A <sub>RMS</sub>
3026	±2 A <sub>RMS</sub>	±3 A <sub>RMS</sub>
3043	±2 A <sub>RMS</sub>	±3 A <sub>RMS</sub>
3044	±2 A <sub>RMS</sub>	±3 A <sub>RMS</sub>
30445	±2 A <sub>RMS</sub>	±3 <sup>5</sup> A <sub>RMS</sub>
3078	±2 A <sub>RMS</sub>	±3 <sup>6</sup> A <sub>RMS</sub>
3178	±2 A <sub>RMS</sub>	±3 A <sub>RMS</sub>
31785	±2 A <sub>RMS</sub>	±3 <sup>7</sup> A <sub>RMS</sub>
3444	±2 A <sub>RMS</sub>	±3 A <sub>RMS</sub>

<sup>&</sup>lt;sup>1</sup> Pulse Amplitude 6%. Tested using industry standard simulator.

<sup>&</sup>lt;sup>2</sup> Pulse Amplitude 1% to 0.1%. Tested using industry standard simulator.

<sup>&</sup>lt;sup>3</sup> Low Perfusion simulator accuracy specification based on BCI<sup>®</sup> 1302.

<sup>&</sup>lt;sup>4</sup>Low Perfusion simulator accuracy specification based on BCI® 3026.

<sup>&</sup>lt;sup>5</sup> Low Perfusion simulator accuracy specification based on BCI® 3044.

<sup>&</sup>lt;sup>6</sup> Pulse Amplitude 1% to 0.3%. Tested using industry standard simulator.

<sup>&</sup>lt;sup>7</sup>Low Perfusion simulator accuracy and specification based on BCI® 3178.

# Pulse Amplitude Index for the WW1020 Oximeter

Range: 0.03% to 20.00% 6 (0.01% increments)

Pulse Amplitude Index is defined as PI = (100 \* AC)/DC where AC is the alternating current (pulsatile component of the signal) and DC is direct current (non-pulsatile component of the signal). It is a relative measure of pulse-signal strength over time at a pulse oximeter

monitoring site, and is non-pulsatile in nature.

Display: 9-segment green / yellow LED bargraph, logarithmic scale

Display Update Rate: 10 Hz

The oximeter will display dashes (Invalid data) for SpO<sub>2</sub> and PR when the PI value is below 0.03%.

Low perfusion performance is verified by simulator testing.

The PI value maps to a 9-segment bar graph as shown below. The two lowest bars (1&2) are bicolor (Yellow & Green), and bars 3 through 9 are Green.

PI From Oximeter	0.00- 0.07	0.08- 0.15	0.16- 0.31	0.32- 0.63	0.64- 1.27	1.28- 2.55	2.56- 5.11	5.12- 10.23	10.24- 20.47
Segments Lit	1Y	2Y	3G	4G	5G	6G	7G	8G	9G

# Pulse Amplitude Index for the WW1000 Oximeter

Range: 0.00% to 20.00% 5 (0.2% increments)

Pulse Amplitude Index is defined as PI = (100 \* AC)/DC where AC is the alternating current (pulsatile component of the signal) and DC is direct current (non-pulsatile component of the signal). It is a relative measure of pulse-signal strength over time at a pulse oximeter monitoring site, and is non-pulsatile in nature.

Display: 9-segment green / yellow LED bargraph, logarithmic scale

Display Update Rate: 10 Hz

The PI value maps to a 9-segment bar graph as shown below. The two lowest bars (1&2) are bicolor (Yellow & Green), and bars 3 through 9 are Green.

PI From Oximeter	0.00	>0 - 0.2	>0.2 - 0.4	>0.4 - 0.6	>0.6 - 1.2	>1.2 - 2.6	>2.6 - 5.0	>5.0 - 10.2	>10.2
Segments Lit	1Y	2Y	3G	4G	5G	6G	7G	8G	9G

### **Printer**

Paper: 58mm (2.28 inches), Thermal

Modes: Real Time, Tabular Trend, Graphic Trend

Paper Speed: 12.5 mm/sec

Trend Graphs: Headers print with graphs

<sup>&</sup>lt;sup>6</sup> As tested with Industry Standard Simulator.

<sup>&</sup>lt;sup>5</sup> As tested with Industry Standard Simulator.

# **Serial Data Output**

### **Power Input and Data Connector**

Data transferred through this connector is in a proprietary BCICP1030 format. Format available upon request.

### **Sensor Connector**

ASCII comma delimited string output at 1 Hz. Lines terminated with a Data Type:

carriage return.

Serial Data Protocol: RS232C, 9600 baud, 1 start bit, 8 data bits, 1 stop bit, no parity.

# **Power Requirements**

# **Battery**

Type:

AA (LR6) disposable: 4 Alkaline

Custom rechargeable: Lithium-Ion (L+), 7.4V replaceable rechargeable battery pack.

Use Time:

AA (LR6) disposable: WW1020 - Approximately 26 hours continuous use

WW1000 - Approximately 32 hours continuous use

Custom rechargeable: WW1020 - Approximately 31 hours continuous use (new)

WW1000 - Approximately 54 hours continuous use (new)

Charge Time:

AA (LR6) disposable: Not rechargeable.

100'" compan Custom rechargeable: Fast charges in approximately 3 hours. Charge time affected by input

power source and device loading. See Chapter 4: Operating Instructions.

Charge Cycles: 300 to 80% capacity

(Custom rechargeable)

### **AC Charger**

WW1095 30 Watt AC Power Supply: 9V, 3A output, Input of 100-240 VAC 50Hz, 60Hz.

### **USB**

WW1089 USB Interface Cable: Input: 5V, 500mA max (USB powered source)

Output: 9V, 230mA max to oximeter.

Length: Maximum 5 meters (16.4 feet)

### **Monitor Dimensions**

Width: 85 mm (3.3 inches) Height: 154 mm (6.1 inches) Depth: 45 mm (1.7 inches)

Weight: 340 grams (12 ounces) with four (4) AA batteries

369 grams (13 ounces) with rechargeable battery pack

## **Dock Dimensions**

DIMENSION	WITHOUT PRINTER	WITH PRINTER
Width:	107 mm (4.2 inches)	160 mm (6.3 inches)
Height:	84 mm (3.3 inches)	84 mm (3.3 inches)
Depth:	109 mm (4.3 inches)	109 mm (4.3 inches)
Weight:	570 grams (20 ounces)	850 grams (30 ounces)

# **Auxiliary Inputs/Outputs**

Sensor: DB9

Data or Power Input

Connector: Non-standard 16 pin docking connector for power and data.

# **Environmental**

**Operating Temperature** 

Oximeter and accessories: 0°C to 55°C (32°F to 131°F)

Printer: 0°C to 50°C (32°F to 122°F)

Power Supply: 0°C to 40°C (32°F to 104°F)

Li+ battery charging: 5°C to 45°C (41°F to 113°F)

**Operating Humidity** 

Oximeter and accessories: 15 to 95% (non-condensing)

Printer: 20 to 85% (non-condensing)

Power Supply: 5 to 95% (non-condensing)

Storage Temperature

Oximeter and accessories:  $-40^{\circ}$ C to  $+75^{\circ}$ C ( $-40^{\circ}$ F to  $+167^{\circ}$ F)

WW1090 LI-Ion rechargeable

battery pack:  $-20^{\circ}$ C to  $+60^{\circ}$ C ( $-4^{\circ}$ F to  $140^{\circ}$ F)

Printer: -25°C to +70°C (-13°F to +158°F)

Power Supply:  $-10^{\circ}$ C to  $+70^{\circ}$ C (14°F to 158°F)

Storage Humidity

Oximeter and accessories: 10 to 95% (non-condensing)

Printer: 10 to 90% (non-condensing)

Power Supply: 5 to 95% (non-condensing)

Altitude: 3050 m (10,000 ft) max
Shock and vibration: ISO 9919 transport rated

NOTE! The monitor may not meet performance specifications when stored or used outside the temperature and humidity ranges listed above.

# **Equipment Classification**

Type of Protection Against Electric

shock: Class II or Internally Powered Mode of operation: Spot Check (non-continuous)

**Degree of Protection Against ingress** 

of Liquids: IPX2, drip proof

Degree of Mobility: Portable

Degree of Protection Against Electric

Shock: Type BF

Electromagnetic classification: CISPR 11 Group1, Class B, see Appendix A: Guidance and

Manufacturer's Declaration.

# **Design Standards**

EN60601-1 / IEC 60601-1 Safety:

an Allien 100" company EMC: EN60601-1-2 / IEC 60601-1-2

SpO<sub>2</sub>:

FDA Draft Guidance for Pulse Oximeters, July 2007

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# **Appendix A: Guidance and Manufacturer's Declaration**

### **Guidance and Manufacturer's Declaration**

The WW1020/WW1000 pulse oximeter is intended for use in the electromagnetic environment specified in the tables within this appendix.

NOTE! The WW1020/WW1000 pulse oximeter system must be put into service according to the provided EMC information to ensure proper operation.

### **Electromagnetic Emissions - Emissions Test**

### **GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS**

The WW1020/WW1000 pulse oximeter is intended for use in the electromagnetic environment specified below. The customer or end user of the WW1020/WW1000 pulse oximeter should ensure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF emissions CISPR 11	Group 1	The WW1020/WW1000 pulse oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The WW1020/WW1000 pulse oximeter is suitable for use in all establishments,
Harmonic emissions IEC 61000-3-2	Class A	including domestic establishments and those directly connected to the public low-voltage
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	power supply network that supplies buildings used for domestic purposes.

# **Electromagnetic Immunity - Immunity Test**

## **GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY**

The WW1020/WW1000 pulse oximeter is intended for use in the electromagnetic environment specified below. The customer or end user of the WW1020/WW1000 pulse oximeter should ensure that it is used in such an environment.

IMMUNITY TEST Electrostatic	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL ±6 kV contact	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE Floors should be wood,
discharge (ESD)	±8 kV air	±8 kV air	concrete or ceramic tile.  If floors are covered with synthetic material, the relative humidity should be
Electrical fast	±2 kV for power supply	±2 kV for power	at least 30%.  Mains power quality should
transient/burst	lines.	supply lines.	be that of typical commercial or hospital environment.
IEC 61000-4-4	±1 kV for input/output lines ±1 kV differential mode	±1 kV for input/ output lines ±1 kV differential	Maka may yang iku ahay la
Surge IEC 61000-4-5	±1 kV dillerential mode	mode	Mains power quality should be that of typical commercial or hospital environment.
	±2 kV common mode	±2 kV common mode	00
Voltage dips, short interruptions, and voltage variations on power supply input lines	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle <40% U <sub>T</sub>	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle <40% U <sub>T</sub>	Mains power quality should be that of typical commercial or hospital environment. If the user of the WW1020/WW1000
IEC 61000-4-11	(>60% dip in U <sub>T</sub> ) for 5 cycles	(>60% dip in U <sub>T</sub> ) for 5 cycles	pulse oximeter requires continued operation during power mains interruptions,
	<70% U <sub>T</sub> (>30% dip in U <sub>T</sub> ) for 25 cycles	<70% U <sub>T</sub> (>30% dip in U <sub>T</sub> ) for 25 cycles	it is recommended that the WW1020/WW1000 pulse oximeter be powered from an uninterruptible power
	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 sec	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 sec	supply or a battery.
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital
IEC 61000-4-8			environment.

Note: U<sub>T</sub> is the a.c. mains voltage prior to application of the test level.

### **GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY**

The WW1020/WW1000 pulse oximeter is intended for use in the electromagnetic environment specified below. The customer or end user of the WW1020/WW1000 pulse oximeter should ensure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
IMMUNITY TEST	LEVEL	LEVEL	Portable and mobile RF communication equipment should be used no closer to any part of the WW1020/WW1000 pulse oximeter, including cable, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz 2 Hz Modulation	3 V/m	d=1.2 $\sqrt{P}$ 80 MHz to 800 MHz d=2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz
	20 V/m 80 MHz to 2.5 GHz 1kHz Modulation	20 V/m	$d = 0.18\sqrt{P}$ 80 MHz to 800 MHz $d = 0.35\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. b
			Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>&</sup>lt;sup>a</sup> Field strengths from fixed RF transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the WW1020/WW1000 pulse oximeter is used exceeds the applicable RF transmitter compliance level above, the WW1020/WW1000 pulse oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the WW1020/WW1000 pulse oximeter.

 $<sup>^{</sup>m b}$  Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

# **Recommended Separation Distances**

# RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE WW1020/WW1000 PULSE OXIMETER

The WW1020/WW1000 pulse oximeter is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the WW1020/WW1000 pulse oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WW1020/WW1000 pulse oximeter as recommended below, according to the maximum output power of the communication equipment.

RATED MAXIMUM OUTPUT POWER	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER m					
OF TRANSMITTER		80 MHz to 800 MHz			to 2.5 GHz	
W	150 kHz to 80 MHz d = 1.2√P	3 V/m d=1.2√P	20 V/m d = 0.18√P	3 V/m d=2.3√P	20 V/m d = 0.35√P	
0.01	.12	0.12	0.02	0.23	0.04	
0.1	.38	0.38	0.06	0.73	0.11	
1	1.2	1.20	0.18	2.30	0.35	
10	3.8	3.79	0.57	7.27	1.11	
100	12	12.00	1.80	23.00	3.50	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The following is a list of cables, transducers and accessories used with the WW1020/WW1000 pulse oximeter.

WARNING! Use of accessories, transducers and cables other than those specified below may result in increased emissions or decreased immunity of the systems.

### **BCI®** Accessories

Dei Accessories	
CAT. NO.	DESCRIPTION
WW1025	Docking Station
WW1026	Printer (Must be used with Docking Station WW1025)
WW1089	USB interface cable
WW1090	Rechargeable battery pack, LI-lon
WW1095	Universal AC mains adapter - 30W
1300	Sensor, Oximetry, Disposable, Adult Finger
1301	Sensor, Oximetry, Disposable, Pediatric. Finger, 15-45 kg
1302	Sensor, Oximetry, Disposable, Neonate/Small Infant, < 3 kg*
1303	Sensor, Oximetry, Disposable, Infant, 3-15 kg
3025	Sensor, Oximetry, Wrap, Infant, 3-15 kg
3026	Sensor, Oximetry, Wrap, Neonate/Small Infant, < 3 kg*
3043	Sensor, Oximetry, Universal 'Y'
3044	Sensor, Oximetry, Finger
30445	Spot Check Sensor, Reusable, Adult
WW3078	Sensor, Oximetry, Ear
3178	Sensor, Pediatric Finger, 5-45 kg
31785	Spot Check Sensor, Reusable, Pediatric
3311	Cable, Oximetry, 1.5 m (5 feet)
3339	PC adapter cable
3350	Printer adapter cable
3444	Sensor, Oximetry, Finger, Comfort Clip®

<sup>\*</sup> The BCI® 1302 and 3026 oximetry sensors should not be used on neonatal patients with the WW1000 monitor. Testing has not been conducted for the WW1000 for patients less than 30 days old. These sensors may, however be used on older patients.

WARNING! The WW1020/WW1000 pulse oximeter should not be used adjacent to other medical equipment. If such use is necessary, the system should be observed to verify normal operation in the configuration it will be used.

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**EC REP** Authorized Representative (as defined by the Medical Device Directive):

Smiths Medical International Ltd. Phone: (44) 1923 246434 Colonial Way, Watford, Hertfordshire, Fax: (44) 1923 240273

WD24 4LG, UK

Australian Representative:

Smiths Medical Australasia Pty. Ltd. Tel: +61 (0) 7 3340 1300

61 Brandl Street, Eight Mile Plains,

QLD 4113, Australia

Manufactured By
Smiths Medical PM, Inc.
N7W22025 Johnson Drive
Waukesha, WI 53186-1856 USA

MEDICAL EQUIPMENT



WITH RESPECT TO ELECTRIC SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL60601-1, IEC60601-1,
CAN/CSA C22.2 NO. 601.1